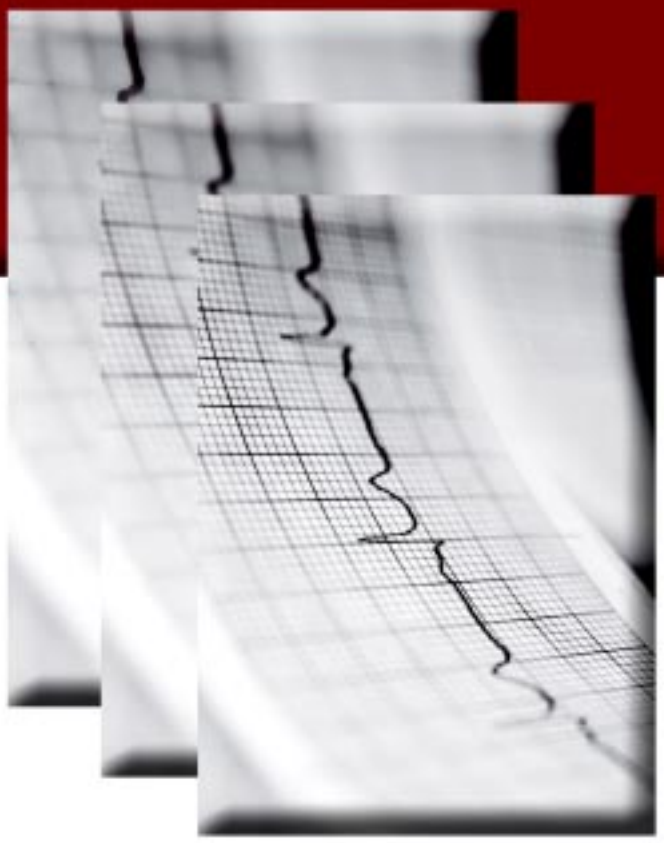
Advisory Committee on Outcome Assessment in Cardiovascular Care



James Scheuer, M.D., Chairman
Steering Committee

Final Report on Interventional Cardiology

June 2003

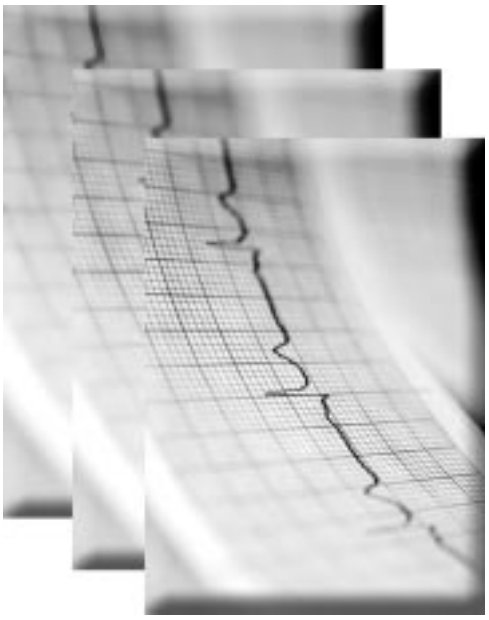
Maryland Health Care Commission

Donald E. Wilson, M.D., MACP
Chairman

This Final Report of the Advisory Committee on Outcome Assessment in Cardiovascular Care was accepted at the June 19, 2003 meeting of the Maryland Health Care Commission.

Advisory Committee on Outcome Assessment in Cardiovascular Care

Final Report on Interventional Cardiology



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Division of Health Resources

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Executive Summary

Improvements in the technique of angioplasty coupled with expanded indications have increased the number of patients receiving this therapy over the past decade. Maryland hospitals performed almost 12,000 percutaneous coronary intervention (PCI) or angioplasty cases in 2002. There are generally two types of angioplasty procedures. While the large majority of angioplasty procedures are performed as elective procedures, angioplasty is also used as a primary means of urgent revascularization in the treatment of certain patients with acute ST-segment elevation myocardial infarction (MI). When angioplasty is used to treat certain acute MI patients, rather than thrombolytic therapy, the procedure is referred to as primary angioplasty.

The Subcommittee on Interventional Cardiology was formed to assist the Advisory Committee on Outcome Assessment in Cardiovascular Care in reviewing key State health planning and regulatory policies regarding PCI: the limited exemption policy permitting hospitals without on-site cardiac surgery backup to perform primary angioplasty for patients with acute ST-segment elevation MI under the protocols of the C-PORT project; the requirement for on-site cardiac surgical backup for elective PCI; the appropriateness of considering a pilot research project to study the safety and efficacy of elective angioplasty without on-site cardiac surgery backup; and, the recommended minimum utilization threshold for elective angioplasty. The findings and recommendations of the Interventional Cardiology Subcommittee were reviewed and endorsed by the Steering Committee of the Advisory Committee on Outcome Assessment in Cardiovascular Care on June 2, 2003. Two Steering Committee members submitted dissenting reports on the interventional cardiology recommendations. The Maryland Health Care Commission accepted the Advisory Committee's *Final Report on Interventional Cardiology* on June 19, 2003.

The findings and recommendations of the Interventional Cardiology Subcommittee as reviewed and endorsed by the Steering Committee are summarized below:

ACUTE ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION

- PRE-HOSPITAL MANAGEMENT OF ACUTE ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION

The Maryland Institute for Emergency Medical Services (MIEMSS) should develop and implement a protocol that will triage appropriate acute MI patients to a primary angioplasty center. A patient who meets the triage category of the protocol should be transported to a primary angioplasty center capable of offering interventional cardiology services rather than the "closest" hospital, provided the time to treatment is not significantly increased. Provided that the time to treatment is not increased, the triage should be directed to the "closest" PCI hospital with cardiac surgery backup on-site.

- HOSPITAL MANAGEMENT OF ACUTE ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION

The superiority of primary PCI when compared to thrombolytic therapy for the treatment of acute ST-segment elevation MI has been demonstrated in a large number of studies. The Subcommittee on Interventional Cardiology believes that the available evidence suggests that when possible a reperfusion strategy of coronary intervention is preferable to thrombolytic therapy for patients with acute ST-segment elevation MI. Given the safety and effectiveness of primary PCI for this group of patients, the subcommittee developed recommendations regarding: institutional, physician, and program development requirements for a primary angioplasty center program; minimum and optimal annual volume of procedures for a primary angioplasty program; patient groups suitable for primary angioplasty in settings without on-site cardiac surgery; and process and outcome measures for on-going quality assessment.

For all programs, it is recommended that primary PCI be available 24 hours per day, seven days per week. This recommendation reflects several considerations. Because medical research has established that primary angioplasty is the preferred approach for treating patients with acute ST-segment elevation MI, it is important that this reperfusion strategy be routinely available. Of equal importance, to ensure optimal patient outcomes, is the need to provide primary PCI on a timely basis, preferably within a door-to-balloon time of 120 minutes or less. The emergent nature of acute ST-segment elevation MI patients combined with the need to provide this intervention rapidly requires hospitals providing primary PCI to have in place a detailed logistics plan involving the emergency department, catheterization laboratory, and CCU that can ensure the availability of this service on a 24/7 basis. As the pre-hospital management component for acute ST-segment elevation MI patients is refined and implemented in Maryland, it is also important to consider resource availability from a system of care perspective. For areas of the state with more than one primary PCI facility, it may be possible to ensure the availability of primary angioplasty on a 24/7 basis with a rotating on-call schedule among institutions.

- INSTITUTIONAL, PHYSICIAN, AND PROGRAM DEVELOPMENT REQUIREMENTS FOR A PRIMARY ANGIOPLASTY PROGRAM

The subcommittee believes that the recommended requirements for institutional and physician resources should apply to all programs designated as primary angioplasty centers. In addition, for the initiation of a new primary angioplasty center program, a hospital should complete a program development phase that establishes standards, trains staff, develops detailed logistics, and establishes a quality and error management system.

Institutional Resources

- All institutions should provide primary PCI as routine, treatment of choice for all appropriate acute MI patients 24 hours per day, seven days per week.
- All institutions should provide primary PCI as soon as possible and not to exceed 120 minutes from patient arrival (i.e., door-to-balloon time of ≤ 120 minutes) for 80 percent of appropriate patients.

- All institutions should have adequate physician, nursing, and technical staff to provide cardiac catheterization laboratory and coronary care unit services to acute MI patients 24 hours per day, seven days per week.
- All institutions should have a written commitment by hospital administration signed by the hospital president to support the program.
- All institutions should design and implement a formal continuing medical education program for staff, particularly in the cardiac catheterization laboratory and coronary care unit.
- For hospitals without on-site cardiac surgery there must be a formal, written agreement with a tertiary institution that provides for unconditional transfer of patients for any required additional care, including emergent or elective cardiac surgery or PCI, for hospitals performing primary PCI without on-site cardiac surgery; and a formal, written agreement with an advanced cardiac life support emergency medical services provider that guarantees arrival of the air or ground ambulance within 30 minutes of a request for patient transport by hospitals performing primary PCI without on-site cardiac surgery.

Physician Resources

- Physicians who perform primary PCI should meet the ACC/AHA criteria for competency of 75 or more total PCI cases per year.
- Physicians newly out of fellowship (less than three years) should have completed a minimum of 50 acute MI's during their fellowship training or 10 proctored cases before being allowed to perform primary PCI alone.
- Physicians who perform primary PCI should agree to participate in an on-call schedule.
- Physicians who perform primary PCI should meet the credentialing criteria for the institution.

Initiation of a New Primary Angioplasty Center Program

- The Maryland Health Care Commission should establish an application process to review requests submitted by hospitals seeking approval to provide primary PCI services without on-site cardiac surgery services.
- All institutions should demonstrate that they have a minimum of 60-65 and optimally 85-90 acute ST-segment elevation MI's annually.
- Because primary PCI is a strategy of care involving a team of health care professionals in multiple care areas, all institutions should begin providing this service only after completing a development program that attends to setting of standards, training of staff, development of logistics and implementation of a formal quality and error management program. The application submitted to the Commission should describe in detail how the hospital proposes to undertake and complete a development program, which may include collaboration with an established primary PCI program.

➢ Relationship Between Volume of Primary Angioplasty Procedures and Outcome

While limited data are now available on the relationship between volume of procedures and outcome, the subcommittee believes that under ideal circumstances the benefits of primary PCI are likely best achieved when a minimum of 49 primary PCI cases are performed. Assuming that as few as 80 percent of potential cases are taken to the catheterization laboratory as recommended in the earlier discussion regarding Institutional Resources and adjusting that number to reflect cases likely to undergo primary PCI, an institution would require a minimum of at least 85-90 acute ST-segment elevation MI's annually to ensure that 49-52 primary angioplasty procedures are performed. A program performing at least 49 cases annually, or approximately one case per week, is more likely to have developed the clinical expertise and operational pathways for timely and effective reperfusion of acutely ill patients.

If, however, rapid access to a program doing 49 cases is not available, then a site performing 36 or more cases/year is acceptable. An institution would require a minimum of at least 60-65 acute ST-segment elevation MI's annually to ensure that 35-37 primary angioplasty procedures are performed. This approach acknowledges important regional differences in access to primary PCI services. The lower volume standard should only be considered in areas of the state where access to a high volume program is not readily available. The optimal and minimum recommended volume guidelines for primary PCI should be reevaluated by the Commission as additional data becomes available on the relationship between volume of procedures and outcome.

➢ Patient Groups Suitable for Primary Angioplasty in Settings without On-Site Cardiac Surgery

The Subcommittee on Interventional Cardiology believes that the following types of patients can be considered for emergency PCI in settings without on-site cardiac surgery:

- ST-segment elevation MI (or new LBBB or ST-depression V1-V2 compatible with true posterior infarction) that are thrombolytic eligible or thrombolytic ineligible.
- When transfer to a tertiary institution may be harmful for patients with acute myocardial infarction in cardiogenic shock that the treating physician(s) believe, either because the patient is too unstable or because the temporal delay will result in worse outcomes.
- Patients for whom the primary PCI system was not initially available, who received thrombolytic therapy that subsequently failed. These cases should constitute no more than 10 percent of all cases.

➢ Process and Outcome Measures for On-Going Quality Assessment

Monitoring of the outcomes of care for patients presenting with ST-elevation MI will facilitate on-going quality improvement efforts and provide the opportunity to measure program compliance, safety, and effectiveness. This requires that a uniform data set be

developed, collected, and analyzed from all hospitals in Maryland offering primary PCI services. This data set should build upon the elements collected in the C-PORT project.

ELECTIVE PERCUTANEOUS CORONARY INTERVENTION

The current ACC/AHA national guidelines for percutaneous coronary intervention (PCI) recommend that hospitals performing elective PCI have cardiac surgery services available on-site. At institutions without on-site cardiac surgical backup, the ACC/AHA classifies elective angioplasty as Class III meaning there is evidence and/or general agreement that the procedure/treatment is not useful/effective and in some cases may be harmful. While the limited research conducted has found that it is feasible to perform elective procedures in hospitals without cardiac surgical backup on-site, the small sample of patients studied restricts the extent to which results can reasonably support modifying current planning policies governing the organization of elective PCI services. There has been no clinical trial directly comparing the outcomes of elective PCI performed in hospitals with on-site cardiac surgery with the outcomes of elective PCI performed in hospitals without on-site cardiac surgery. Moreover, methods for identifying those patients who might be best suited for elective PCI in the absence of on-site surgical backup have not been described or validated.

Given the limited body of evidence now available, the Interventional Cardiology Subcommittee believes that Maryland should continue to require that hospitals providing elective angioplasty services have cardiac surgical services on-site. This policy direction, which should continue to be reviewed periodically, should remain in place until clinical evidence confirms the efficacy and safety of elective angioplasty without on-site cardiac surgery backup.

PILOT PROJECT STUDY ON THE NEED FOR ON-SITE CARDIAC SURGICAL BACKUP FOR ELECTIVE PCI

- PILOT PROJECT STUDY TO ASSESS APPROPRIATENESS OF MODIFYING CURRENT POLICY REGARDING AVAILABILITY OF ON-SITE CARDIAC SURGERY FOR CERTAIN GROUPS OF ELECTIVE ANGIOPLASTY PATIENTS

In discussing whether Maryland should support research concerning the need for on-site surgical backup for elective PCI, the Subcommittee on Interventional Cardiology considered a number of issues. While the ability to provide primary angioplasty offered the potential of some clinical benefit to acute MI patients, there is no similar clinical benefit likely with respect to elective cases. On the other hand, the subcommittee recognized the potential benefit to rural hospitals that want to provide primary angioplasty of being able to strengthen program volumes by offering elective procedures. Moreover, the subcommittee recognized the potential value of enhanced convenience for patients, families, and physicians.

Acknowledging there is no clinical benefit for elective patients undergoing angioplasty without on-site surgery, the subcommittee recognizes that the question of the need for on-site cardiac surgical backup for elective angioplasty procedures is the subject of considerable national debate. Given the likelihood that this debate will continue, it is important to consider

whether Maryland hospitals should participate in studying the issue given experience with the C-PORT study. Given these considerations, the Interventional Cardiology Subcommittee believes that it would be appropriate for the Maryland Health Care Commission to consider supporting a waiver for a well-designed, peer reviewed research proposal to study the safety of elective PCI without on-site cardiac surgery. This research proposal must be capable answering questions regarding the need for on-site cardiac surgical backup for elective PCI using accepted principles of scientific investigation. Hospitals wishing to participate in this research proposal could apply to the Commission for this waiver.

- CONSIDERATIONS REGARDING THE DESIGN AND IMPLEMENTATION OF AN ELECTIVE PCI PILOT PROJECT STUDY

The Interventional Cardiology Subcommittee believes that a research proposal to study elective PCI without on-site cardiac surgery must, at a minimum, include the following components: (1) detailed description of the research design and methods; (2) protocol for including patients in the elective PCI research study; (3) need for institutional review board review; (4) criteria for participating hospital sites and physicians (including minimum volume standards for the practitioner and institution); (5) data collection and management plan; (6) timetable for initiating and completing the study; and (7) source and amount of funding necessary to conduct the research study.

The subcommittee also recommends that the Maryland Health Care Commission appoint an advisory committee to review and provide advice on any research proposal submitted to the Commission to study elective angioplasty without on-site cardiac surgery backup. In addition, the Commission should establish an advisory committee to assist in interpreting the results of this and/or other research on the safety of elective PCI without on-site cardiac surgery and to advise the Commission on the appropriateness of modifying State health planning policy governing the requirement to have cardiac surgical services on-site for elective angioplasty. The subcommittee also recommends that the Commission analyze the system impact, including access, cost, and quality implications, of elective angioplasty being performed in hospitals without on-site cardiac surgery.

VOLUME –QUALITY RELATIONSHIP FOR ELECTIVE ANGIOPLASTY

The recently updated ACC/AHA national guidelines recommend a minimum institutional volume of 200 to 400 procedures annually and an optimal institutional volume of more than 400 procedures annually. Those current guidelines recommend that PCI procedures be performed by higher volume operators ($\geq$ 75 cases annually) with advanced technical skills (e.g., subspecialty certification) at well-equipped institutions with experienced support staff performing at least 400 procedures annually.

Higher volume PCI programs have been shown to experience lower mortality rates and lower risk of emergency CABG surgery. Given these findings, the subcommittee believes that PCI programs should perform a minimum of 200-400 procedures annually. Consistent with ACC/AHA recommendations, the subcommittee concludes that for optimal patient outcome an institutional volume of more than 400 PCI procedures should be performed annually.

STEERING COMMITTEE REVIEW AND ENDORSEMENT

At its June 2, 2003 meeting, the Steering Committee endorsed the findings and recommendations of the Interventional Cardiology Subcommittee regarding acute ST-segment elevation MI with the suggestion that the Commission consider using the metrics outlined in the requirements for primary PCI programs as potential data elements for the acute care hospital report card. The Steering Committee further recommended that the Commission review and evaluate the recommendations regarding primary PCI on at least a yearly basis to ensure that as research and knowledge change (e.g., maximum door-to-balloon times, minimum volume requirements) the recommendations remain current. The Steering Committee also endorsed the findings and recommendations of the Interventional Cardiology Subcommittee regarding elective angioplasty with dissenting opinions submitted by two members. In its review of the process recommended by the subcommittee for considering a research proposal to study the safety of elective angioplasty in hospitals without on-site cardiac surgery backup, the Steering Committee suggested that the specifications include consideration of the need for an adequate control group and power analysis to determine the appropriate number of participants in the research study.

I. Introduction

Background

In Maryland and in the United States as a whole, heart disease is the leading cause of death. During 2000, diseases of the heart claimed about 12,000 lives and accounted for almost one-third of all deaths in Maryland. Over the past several decades, mortality due to diseases of the heart has declined dramatically in Maryland as well as in the United States. Although the complexity of heart disease makes it difficult to determine the precise reasons for the decline in mortality, it is likely that increased emphasis on prevention and improvements in medical care, particularly for patients with acute MI have contributed to the reduction.

Over the next decade, the baby boom generation will contribute to substantial increases in the older population most at risk for developing heart disease. While awareness of the importance of healthier lifestyles can be expected to moderate future utilization increases, for some patients the impact of minimizing adverse risk factors will be to delay the onset rather than to prevent the development of heart disease. In addition, more people are surviving heart attacks. Reduced mortality from heart attacks has resulted in an increased incidence of congestive heart failure (CHF) in the older patient population. This demographic shift combined with continuing advances in the treatment of heart disease suggests the need to ensure that public policy effectively addresses quality of care, access, and cost issues involving specialized cardiac care services.

To guide public policy governing specialized cardiac care services, the Maryland Health Care Commission prepares a State Health Plan that contains planning policies, a need projection for open heart surgery services, and criteria and standards for reviewing certificate of need (CON) applications. Under Maryland health planning law, the establishment of new open heart surgery and therapeutic catheterization programs requires CON approval. The updated Maryland State Health Plan chapter, COMAR 10.24.17, governing cardiac surgery and therapeutic catheterization services adopted by the Commission became effective in May 2001. In developing this plan, the Commission recognized the need to establish an Advisory Committee on Outcome Assessment in Cardiovascular Care to promote the development of a Maryland model for continuous quality improvement. In early 2002, the Commission took steps to organize and appoint this Advisory Committee.

Purpose of the Advisory Committee

The purpose of the Advisory Committee on Outcome Assessment in Cardiovascular Care is to study and develop recommendations to the Maryland Health Care Commission on establishing an on-going, statewide quality improvement program in cardiovascular care. The goals of this effort are to identify baseline indicators to measure current performance, design an approach for continuous quality improvement, and evaluate options for funding a statewide quality improvement effort. In addition to targeting performance improvement for care currently provided, the Commission is interested in better understanding how the organization of cardiac

services impacts quality of care and access considerations. Key tasks involved in this project are outlined below:

- Identify quality measures and risk adjustment methods and develop recommendations on the structure and content of a Maryland Cardiovascular Care Data Reporting System designed to support outcome assessment;
- Study available models for quality improvement in cardiovascular care, focusing initially on cardiac surgery and coronary angioplasty services, and develop recommendations on the appropriate governance, organizational structure, staffing, and funding for an on-going outcome assessment process for cardiovascular care in Maryland;
- Develop a research agenda to advance the understanding of how cardiac care services should be organized to improve outcomes, including, but not limited to, developing an evidence-based approach to reviewing policies governing the location of primary and elective angioplasty services; and
- Identify strategies for developing a statewide inter-hospital transport system for specialized cardiac care services and recommend actions that public and private sector organizations should take to implement an inter-hospital transport system.

Organizational Structure

In order to get broad participation in the process, and to focus available expertise in specific areas, the Commission structured the Advisory Committee to include a Steering Committee and four subcommittees (refer to Figure 1). Steering Committee members were appointed by Donald E. Wilson, M.D., Chairman of the Maryland Health Care Commission, after considering nominations received from a wide range of organizations, including hospitals, state and national professional associations, state government, and health care policy research organizations. The Steering Committee reports directly to the Commission and is responsible for preparing Interim and Final Reports summarizing its findings and recommendations.

The subcommittees report to the Steering Committee. Each subcommittee includes members from the Steering Committee as well as other interested individuals. Members of the Steering Committee were appointed to chair each subcommittee. The Commission sought participants from a wide range of organizations, including the Maryland Department of Health and Mental Hygiene, the Maryland Institute for Emergency Medical Services Systems, Maryland acute care hospitals, and state and national professional associations, in appointing subcommittee members. The four subcommittees established to assist the Steering Committee include:

•Subcommittee on Quality Measurement and Data Reporting

This subcommittee studied available models for quality improvement in cardiovascular care and will develop recommendations to the Steering Committee on the approach that should be used in Maryland.

•Subcommittee on Interventional Cardiology

This subcommittee conducted a detailed review of the results of the Cardiovascular Patient Outcomes Research Team (C-PORT) project and developing recommendations on the types of hospitals that should perform primary angioplasty. In addition, the subcommittee reviewed the policy of providing elective angioplasty services only in hospitals with on-site cardiac surgical services.

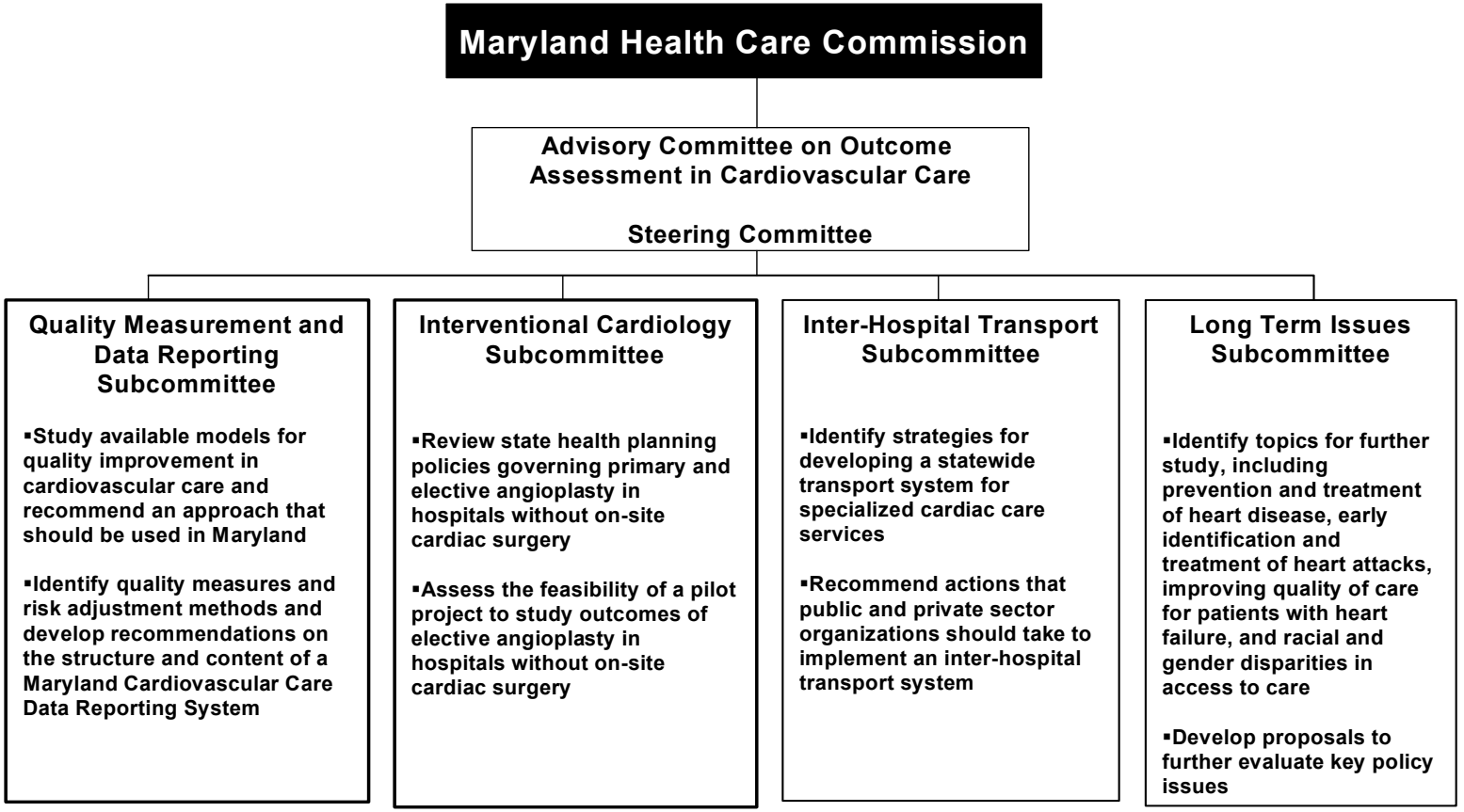
•Subcommittee on Inter-Hospital Transport

The Subcommittee on Inter-Hospital Transport studied strategies for improving the transport of cardiac patients between hospitals. The subcommittee identified potential strategies for developing a statewide inter-hospital transport system for specialized cardiac care services and recommending actions that public and private sector organizations should take to implement an inter-hospital transport system.

•Subcommittee on Long Term Issues

The focus of this subcommittee is on identifying topics for further study, developing proposals to further evaluate key policy issues, and developing a long-range, evidence-based approach for assessing the impact of changes in cardiovascular services. This subcommittee considered the feasibility and advisability of developing programs that deal with the other issues in cardiovascular health and disease, such as screening, primary and secondary prevention, hypertension, and diabetes care.

Figure 1 **Organizational Structure: Advisory Committee on Outcome Assessment in Cardiovascular Care**



Steering Committee Composition

The Steering Committee of the Advisory Committee on Outcome Assessment in Cardiovascular Care is composed of 18 members with expertise in the organization, delivery, and financing of cardiovascular care, including the disciplines of cardiology, cardiac surgery, health services research, emergency medical services, and health care administration (see Figure 2). The Honorable Nelson J. Sabatini, Secretary for the State of Maryland for Health and Mental Hygiene is an ex-officio member of the Steering Committee. Representatives include Maryland providers of specialized cardiac care services as well as representatives with regional and national expertise in the collection and/or analysis of data to support policy development in the area of specialized cardiac care services. (Appendix A provides brief biographies for Steering Committee members.)

James Scheuer, M.D., Professor of Medicine and University Chairman Emeritus at the Albert Einstein College of Medicine/Montefiore Medical Center in New York, Chairs the Steering Committee. Dr. Scheuer received his medical degree from Yale University Medical School. He served his internship at Bellevue Hospital in New York and his residency at Mount Sinai Hospital, also in New York. Dr. Scheuer trained as a National Institutes of Health postdoctoral fellow at New York Hospital, Cornell Medical Center. He is the past president of the New York Cardiological Society and has served on the editorial boards of many medical journals, including *Cardiology*, *Circulation Research*, *Circulation*, and the *American Journal of Cardiology.*

Report Organization

This *Final Report,* which was presented and accepted at the June 19, 2003 meeting of the Maryland Health Care Commission, provides the findings and recommendations of the Steering Committee regarding interventional cardiology. Following the Introduction, the report is organized in four major areas: Acute ST-Segment Elevation MI; Elective PCI; Pilot Project Study on the Need for On-Site Cardiac Surgical Backup for Elective PCI; and Volume-Quality Relationship for Elective PCI. The Appendices include brief biographies of Steering Committee members, a summary of the recommended requirements for primary PCI programs in hospitals with and without on-site cardiac surgery, dissenting opinions from Steering Committee members, and summary minutes of the Steering Committee meetings.

The final recommendations of the Steering Committee on additional issues, including quality measurement and data reporting, inter-hospital transport, and long term issues will be presented to the Maryland Health Care Commission in the fall of 2003.

Figure 2

Advisory Committee on Outcome Assessment in Cardiovascular Care

Steering Committee

Chairman

James Scheuer, M.D.
Professor of Medicine and University Chairman Emeritus
Department of Medicine
Albert Einstein College of Medicine/Montefiore Medical Center
Bronx, New York

Membership

Robert R. Bass, M.D.
Executive Director
Maryland Institute for Emergency Medical Services Systems
Baltimore, Maryland

William A. Baumgartner, M.D.
Cardiac Surgeon
Vice Dean, Clinical Affairs and Cardiac Surgeon-in-Charge
The Johns Hopkins Hospital
Baltimore, Maryland

Luther T. Clark, M.D.
Chief of Cardiology
SUNY Health Sciences Center at Brooklyn
Brooklyn, New York

Donald H. Dembo, M.D.
President, MD Chapter of the American College of Cardiology
Johns Hopkins Cardiology at Timonium
Baltimore, Maryland

James L. Field, DBA
Executive Director, Cardiovascular Roundtable
Advisory Board Company
Washington, D.C.

Scott Friedman, M.D.
Cardiologist
Memorial Hospital of Easton
Easton, Maryland

Bartley Griffith, M.D.
Cardiac Surgeon
University of Maryland Hospital
Baltimore, Maryland

Jeffrey D. Jones, M.D.
Cardiologist
Washington County Hospital
Hagerstown, Maryland

Steve B. Lowenthal, M.D.
Chief Medical Officer
St. Agnes HealthCare
Baltimore, Maryland

Thom Mayer, M.D.
Chairman, Department of Emergency Medicine
Fairfax Hospital
Falls Church, Virginia

Mark G. Midei, MD.
Cardiologist
St. Joseph Medical Center
Towson, Maryland

Luis Mispireta, M.D.
Cardiac Surgeon
Chief, Division of Cardiac Surgery
Union Memorial Hospital
Baltimore, Maryland

Hilary T. O'Herlihy, M.D.
President, MedChi Board of Trustees
Glen Burnie, Maryland

Eugene R. Passamani, M.D.
Cardiologist
Vice President, Quality
Suburban Hospital
Bethesda, Maryland

Honorable Nelson J. Sabatini (Ex-Officio)
Secretary
Department of Health and Mental Hygiene
Baltimore, Maryland

Sidney C. Smith, Jr., M.D.
Director, Center for Cardiovascular Science and Medicine
University of North Carolina Health Care
Chapel Hill, North Carolina

David O. Williams, M.D.
Director, Cardiovascular Laboratory and Interventional Cardiology
Rhode Island Hospital
Providence, Rhode Island

Note: Vahe Kazandjian, Ph.D. served on the Steering Committee until June 200; Georges C. Benjamin, M.D. served as a Ex-Officio member until April 2003.

II. Interventional Cardiology

Background

Improvements in the technique of angioplasty coupled with expanded indications have increased the number of patients receiving this therapy over the past decade. Maryland hospitals performed almost 12,000 percutaneous coronary intervention (PCI) or angioplasty cases in 2002. There are generally two types of angioplasty procedures. While the large majority of angioplasty procedures are performed as elective procedures, angioplasty is also used as a primary means of urgent revascularization in the treatment of certain patients with acute ST-segment elevation myocardial infarction (MI). When angioplasty is used to treat certain acute MI patients, rather than thrombolytic therapy, the procedure is referred to as primary angioplasty.

The Subcommittee on Interventional Cardiology was formed to assist the Advisory Committee on Outcome Assessment in Cardiovascular Care in reviewing key State health planning and regulatory policies regarding PCI. These policies include the requirement for on-site cardiac surgical backup for primary and elective PCI, whether the Commission should consider a pilot research project to study the safety and efficacy of elective angioplasty without on-site cardiac surgery backup, and the recommended minimum utilization threshold for elective angioplasty.

The *State Health Plan: Specialized Health Care Services-Cardiac Surgery and Therapeutic Catheterization Services (COMAR 10.24.17*), effective May 2001, requires that coronary angioplasty services be provided in hospitals with cardiac surgery capabilities. This policy, which reflects the advice of Maryland cardiologists and cardiac surgeons as well as guidelines recommended by medical professional groups, states:

> *Policy 5.0: Percutaneous transluminal coronary angioplasty (PTCA) procedures should only be performed in hospitals with on-site cardiac surgical backup.*

To assess the relative benefits of primary angioplasty versus thrombolytic therapy for the treatment of acute MI, the former Health Resources Planning Commission, a predecessor agency to the Maryland Health Care Commission, approved an exemption from this State Health Plan policy requiring hospitals performing angioplasty to have on-site cardiac surgical backup for the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) project. This exemption, which became effective in January 1996, permits Maryland hospitals participating under the C-PORT study protocol to perform angioplasty without on-site cardiac surgical backup. The exemption for the Atlantic C-PORT project has been extended since that time and the State Health Plan adopted by the Commission in 2001 includes the following policy statement:

> *Policy 5.1: The Commission should maintain the limited exemption policy permitting hospitals without on-site cardiac surgery backup to perform primary angioplasty under the protocols of the C-PORT project.*

Given the Maryland experience with primary angioplasty, the charge to the Subcommittee on Interventional Cardiology included a detailed review of data from the C-PORT project and other

medical research to provide advice on the appropriateness of modifying the State Health Plan policy governing the co-location of PCI and cardiac surgery services for the treatment of patients with acute ST-segment elevation MI.

Whether current health planning policy should be modified to permit Maryland hospitals to participate in a study to assess the safety of performing elective angioplasty without on-site cardiac surgery was another issue considered by the subcommittee. With on-going technical improvements in coronary angioplasty procedures, it is important to review policies governing the requirement for on-site cardiac surgical backup for elective angioplasty cases. The current State Health Plan contains a policy designed to study the safety and efficacy of elective angioplasty in hospitals without on-site cardiac surgery backup:

> *Policy 5.2: The Commission should consider a pilot project to assess whether it would be appropriate to modify current policy regarding the availability of on-site cardiac surgery backup for certain groups of elective angioplasty patients. This pilot project should be designed and implemented as a component of the Advisory Committee on Outcome Assessment in Cardiovascular Care.*

The volume-quality relationship for elective PCI was the final issue considered by the Subcommittee on Interventional Cardiology. To promote effective planning for specialized cardiac care services and ensure quality care, the Commission established the following policy governing minimum utilization levels for angioplasty services in the State Health Plan:

> *Policy 1.4: There should be a minimum of 200 percutaneous transluminal coronary angioplasty procedures performed annually in any institution in which elective angioplasty procedures are performed.*

Interventional Cardiology Subcommittee

➢ Subcommittee Composition

The Subcommittee on Interventional Cardiology included 26 members representing the disciplines of cardiology, cardiac surgery, planning, and emergency medical services. Figure 3 provides a list of Interventional Cardiology Subcommittee members. The subcommittee was chaired by David O. Williams, M.D. Dr. Williams is Director of the Cardiovascular Laboratory and Interventional Cardiology at Rhode Island Hospital in Providence, Rhode Island. He is a Professor of Medicine at the Brown University School of Medicine and a Member of the Cardiac Care Advisory Committee for the Rhode Island State Department of Health. Dr. Williams served on the American College of Cardiology/American Heart Association (ACC/AHA) Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty.

➢ Purpose of the Subcommittee

The Subcommittee on Interventional Cardiology conducted a detailed review of the results of the C-PORT project, the ACC/AHA guidelines, and other relevant studies and developed recommendations on the types of hospitals that should perform primary angioplasty.

In addition, the subcommittee reviewed the policy of providing elective angioplasty services only in hospitals with on-site cardiac surgical services. Specifically, the Subcommittee on Interventional Cardiology studied and developed recommendations to the Steering Committee on four major topics: acute ST-segment elevation MI; elective PCI; pilot project study on the need for on-site cardiac surgical backup for elective PCI; and the volume-quality relationship in elective PCI. The questions considered by the subcommittee for each of these four topic areas were as follows:

ACUTE ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION

- *How do outcomes of primary angioplasty performed in hospitals without on-site cardiac surgery compare with outcomes in hospitals with on-site surgery?*
- *What institutional resources are required for a primary angioplasty program? What are the program development requirements for a primary angioplasty program?*
- *Is there a relationship between volume of primary angioplasty procedures and outcomes? If so, is there a minimum volume of cases that should be performed annually?*
- *Which patient groups are suitable for primary angioplasty in settings without on-site cardiac surgery?*
- *What process and outcome measures should be used for on-going quality assessment?*

ELECTIVE PERCUTANEOUS CORONARY INTERVENTION

- *Is there evidence that current policy restricts availability of elective angioplasty services to Maryland patients?*
- *How do outcomes of elective angioplasty performed in hospitals without on-site cardiac surgery compare with the outcomes of elective angioplasty performed in hospitals with cardiac surgery?*

PILOT PROJECT STUDY ON THE NEED FOR ON-SITE CARDIAC SURGICAL BACKUP FOR ELECTIVE PERCUTANEOUS CORONARY INTERVENTION

- *Should the Commission consider a pilot project study to assess whether it would be appropriate to modify current policy regarding the availability of on-site cardiac surgery backup for certain groups of elective angioplasty patients?*
- *How should this pilot project be designed and implemented? What would be the resource and program development requirements for a participating hospital? What process and outcome measures should be used for on-going quality assessment? Which patient groups would be suitable for inclusion in a pilot program study of elective angioplasty?*

VOLUME-QUALITY RELATIONSHIP IN ELECTIVE PERCUTANEOUS CORONARY INTERVENTION

- *Is there a relationship between volume of elective angioplasty procedures and outcomes? If so, is there a minimum volume of cases that should be performed annually?*

The Subcommittee on Interventional Cardiology held a total of five meetings between September 2002-April 2003. Meetings of the subcommittee were announced and open to the public. At its first meeting on September 4, 2002, the subcommittee members discussed the

charge, structure, and timetable as well as a proposed work plan and process. The second meeting was held on October 16, 2002. The subcommittee had a presentation from Thomas Aversano, M.D. regarding the experience of hospitals participating in the C-PORT trial and registry at that meeting. On February 19, 2003, the subcommittee began discussing the questions posed in its charge regarding primary angioplasty. At the March 10, 2003 meeting, the subcommittee reviewed a draft document summarizing their findings and recommendations regarding acute ST-segment elevation MI and discussed a series of questions on elective PCI. The final subcommittee meeting was held on April 14, 2003. At that meeting, the subcommittee reviewed and suggested changes to the findings and recommendations regarding acute ST-segment elevation MI and elective PCI. (Summary minutes of the subcommittee meetings are provided in the Appendix B of the *Report of the Interventional Cardiology Subcommittee*.)

Figure 3

Advisory Committee on Outcome Assessment in Cardiovascular Care

Interventional Cardiology Subcommittee

Chairman

David O. Williams, M.D.
Director, Cardiovascular Laboratory and
Interventional Cardiology
Rhode Island Hospital
Providence, Rhode Island

Members

Robert R. Bass, M.D.
Executive Director
Maryland Institute for Emergency
Medical Services Systems
Baltimore, Maryland

George Bittar, M.D.
Interventional Cardiologist
Union Memorial Hospital
Baltimore, Maryland

Sridhur Chatrathi, M.D.
Capital Cardiology
Lanham, Maryland

Charles Cummings, M.D.
Cardiologist
Mid-Atlantic Cardiovascular Associates
Westminster, Maryland

Michael Fiocco, M.D.
Cardiac Surgeon
Union Memorial Hospital
Baltimore, Maryland

Candice Fonke, R.N.
Director, Cardiology
Peninsula Regional Medical Center
Salisbury, Maryland

James L. Field, DBA
Executive Director, Cardiovascular Roundtable
Advisory Board Company
Washington, D.C.

Scott Friedman, M.D.
Cardiologist
Memorial Hospital of Easton
Easton, Maryland

Frank Gravino, M.D.
Cardiologist
Holy Cross Hospital
Silver Spring, Maryland

Bartley Griffith, M.D.
Cardiac Surgeon
University of Maryland Hospital
Baltimore, Maryland

William Herzog, M.D.
Associate Professor of Medicine
University of Maryland
Baltimore, Maryland

Roy Leiboff, M.D.
Heart Center of Southern Maryland
Washington, D.C.

Keith M. Lindgren, M.D.
Director of Cardiology
Washington Adventist Hospital
Takoma Park, Maryland

Steve B. Lowenthal, M.D.
Executive Vice President/Chief Medical Officer
St. Agnes HealthCare
Baltimore, Maryland

Mark G. Midei, MD.
Cardiologist
St. Joseph Medical Center
Baltimore, Maryland

Catherine L. Monge
Vice President, Professional & Support
Services
Carroll County General Hospital
Westminster, Maryland

Robin P. Newhouse, R.N.
Nurse Researcher
Johns Hopkins Hospital
Baltimore, Maryland

Stephen H. Pollock, M.D.
Mid-Atlantic Cardiovascular Associates, P.A.
Towson, Maryland

James K. Porterfield, M.D.
Division Head, Cardiology
GBMC HealthCare
Baltimore, Maryland

Bernard Rubin, M.D.
Baltimore Heart
Randallstown, Maryland

(Continued on next page)

Figure 3 (Continued)
Advisory Committee on Outcome Assessment in Cardiovascular Care
Interventional Cardiology Subcommittee

Susheel Sharma, M.D.
Cardiologist
North Arundel Hospital
Glen Burnie, Maryland

Mitchell Schwartz, M.D.
Medical Director, Medicine Initiative
Anne Arundel Medical Center
Annapolis, Maryland

Dominic Seraphin
Vice President
Business Development
St. Joseph Medical Center
Towson, Maryland

Sidney C. Smith, Jr., M.D.
Director, Center for Cardiovascular Science & Medicine
Professor and Chief of Cardiology
University of North Carolina Health Care
Chapel Hill, North Carolina

Karen Stair
Director, Cardiovascular Services
Western Maryland Health System
Cumberland, Maryland

Findings and Recommendations of the Interventional Cardiology Subcommittee

➢ Acute ST-Segment Elevation Myocardial Infarction

The *Maryland State Health Plan: Specialized Health Care Services-Cardiac Surgery and Therapeutic Catheterization Services* includes procedures for exempting certain research projects from the policy requiring co-location of cardiac surgery and angioplasty services. Under these exemption procedures, the former Maryland Health Resources Planning Commission approved a request from Thomas Aversano, M.D. of the Johns Hopkins Medical Institutions to permit selected Maryland hospitals participating in the C-PORT clinical trial to perform primary angioplasty under the protocols of this research project.

Hospitals participating in this research project may perform angioplasty as a primary means of urgent revascularization in the treatment of patients with acute ST-segment MI without the requirement for on-site cardiac surgical backup. This exemption was originally granted for two years from an effective date of January 15, 1996, and has been extended at the request of Dr. Aversano since that time. In 2002, the Maryland Health Care Commission extended the exemption for the C-PORT project through June 2003.[1] From 1996 to 1999, the C-PORT project enrolled patients in a randomized, clinical trial. In its second phase, which began in August 1999, the C-PORT project is functioning as a registry.

Although there remain important questions on the role of primary angioplasty in treating acute MI, this therapy has gained widespread acceptance among cardiologists as the preferred approach for treating acute ST-segment elevation MI when it can be performed rapidly and in the right environment. The Subcommittee on Interventional Cardiology reviewed data from the C-PORT project and other medical research to evaluate the most effective strategies for improving the system of care for patients with acute ST-segment elevation MI. While the primary goal of the subcommittee was to advise the Commission on the appropriateness of modifying the State Health Plan policy governing the co-location of PCI and cardiac surgery services for the treatment of patients with acute ST-segment elevation MI, the subcommittee also considered related issues including pre-hospital management of patients with acute MI. The charge to the Subcommittee on Interventional Cardiology included a series of questions regarding primary PCI. The subcommittee's analysis and recommendations with respect to these questions is provided in this document. The subcommittee recognizes that these findings are based on currently available data. As new data are collected, the subcommittee recommends that these findings be reviewed and modified as appropriate.

[1] In correspondence dated June 24, 2003 to Thomas Aversano, M.D., the Commission's Executive Director, Barbara G. McLean, extended the waiver granted to the C-PORT Project to permit the Commission to act on an updated State Health Plan reflecting the findings and recommendations of the Advisory Committee on Outcome Assessment in Cardiovascular Care.

- **PRE-HOSPITAL MANAGEMENT OF ACUTE ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION**

The Maryland Institute for Emergency Medical Services (MIEMSS) should develop and implement a protocol that will triage appropriate acute MI patients to a primary angioplasty center. Improvements in the technology of electrocardiographic equipment have made it possible for pre-hospital care providers to obtain and transmit 12-lead ECGs. Because this technology offers the benefit of decreasing the time between onset of an MI and definitive treatment, the subcommittee believes that the mobile electrocardiogram is a key element of any plan to improve the system of care for acute ST-segment elevation MI. A patient who meets the triage category of the protocol should be transported to a primary angioplasty center capable of offering interventional cardiology services rather than the "closest" hospital, provided the time to treatment is not significantly increased. Provided that the time to treatment is not increased, the triage should be directed to the "closest" PCI hospital with cardiac surgery backup on-site.

- **HOSPITAL MANAGEMENT OF ACUTE ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION**

The superiority of primary PCI when compared to thrombolytic therapy for the treatment of acute ST-segment elevation MI has been demonstrated in a large number of studies.[2] The Subcommittee on Interventional Cardiology believes that the available evidence suggests that when possible a reperfusion strategy of coronary intervention is preferable to thrombolytic therapy for patients with acute ST-segment elevation MI. Given the safety and effectiveness of primary PCI for this group of patients, the subcommittee considered a number of questions related to the future organization and delivery of primary PCI services in Maryland.

1. Comparison of Primary Angioplasty Outcomes in Hospitals With and Without On-Site Cardiac Surgery

The Subcommittee on Interventional Cardiology examined available data comparing the outcomes of primary angioplasty performed in hospitals without on-site cardiac surgery with outcomes in hospitals with on-site surgery. Some registry studies have suggested that programs without on-site cardiac surgery can safely and effectively provide primary angioplasty in a high-risk population and that outcomes might be similar to those reported from high volume surgical centers.[3] While available research is helpful, there is no controlled randomized trial that addresses this comparison. The subcommittee felt that available data are insufficient to answer this question with confidence. Future

[2] Keeley, EC, Boura, JA, and Grines, CL. Primary angioplasty versus intravenous thrombolytic therapy for acute myocardial infarction: a quantitative review of 23 randomised trials. *The Lancet*. Vol. 361, January 4, 2003:13-20.

[3] Wharton, TP Jr. Primary angioplasty at hospitals with off-site cardiac surgical backup: draft of response to Question 1 of the April 2002 document of the Subcommittee on Interventional Cardiology, Advisory Committee on Outcome Assessment in Cardiovascular Care, p. 2-3.

clinical trials may investigate this subject with results that influence the strategy for managing these patients.

2. Institutional, Physician, and Program Development Requirements for a Primary Angioplasty Program

The Subcommittee on Interventional Cardiology reviewed the recommendations governing operator and institutional requirements for a primary angioplasty program developed by: the ACC/AHA Task Force on Practice Guidelines[4]; Wharton and colleagues; Thomas Aversano, M.D., Principal Investigator for C-PORT; and other relevant publications. Based on this review, the subcommittee believes that the institutional and physician resource requirements should apply to all programs designated as primary angioplasty centers. In addition, for the initiation of a new PCI program, a hospital should complete a program development phase that establishes standards, trains staff, develops detailed logistics, and establishes a quality and error management system.

For all programs, it is recommended that primary PCI be available 24 hours per day, seven days per week. This recommendation reflects several considerations. Because medical research has established that primary angioplasty is the preferred approach for treating patients with acute ST-segment elevation MI, it is important that this reperfusion strategy be routinely available. Of equal importance, to ensure optimal patient outcomes, is the need to provide primary PCI on a timely basis, preferably within a door-to-balloon time of 120 minutes or less. The emergent nature of acute ST-segment elevation MI patients combined with the need to provide this intervention rapidly requires hospitals providing primary PCI to have in place a detailed logistics plan involving the emergency department, catheterization laboratory, and CCU that can ensure the availability of this service on a 24/7 basis. As the pre-hospital management component for acute ST-segment elevation MI patients is refined and implemented in Maryland, it is also important to consider resource availability from a system of care perspective. For areas of the state with more than one primary PCI facility, it may be possible to ensure the availability of primary angioplasty on a 24/7 basis with a rotating on-call schedule among institutions.

The recommended institutional, physician, and program development requirements are as follows (also refer to Appendix C):

a. Institutional Resources

(1) All institutions should provide primary PCI as routine, treatment of choice for all appropriate AMI patients 24 hours per day, seven days per week.

[4] Smith SC, Jr., Dove JT, Jacobs AK, Kennedy JW, Kereiakes D, Kern MJ, Kuntz RE, Popma JJ, Schaff HV, Williams DO. ACC/AHA Guidelines for Percutaneous Coronary Intervention: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty). *Journal of the American College of Cardiology*. Vol. 37, No. 8, June 15, 2001:1-66.

(2) All institutions should provide primary PCI as soon as possible and not to exceed 120 minutes from patient arrival (i.e., door-to-balloon time of ≤ 120 minutes) for 80 percent of appropriate patients.

(3) All institutions should have adequate physician, nursing, and technical staff to provide cardiac catheterization laboratory and coronary care unit services to acute MI patients 24 hours per day, seven days per week.

(4) All institutions should have a written commitment by hospital administration signed by the hospital president to support the program, and be required to:

(i) identify a physician director of interventional cardiology services responsible for defining and implementing credentialing criteria for the catheterization laboratory and for overall primary PCI program management, including responsibility for equipment, personnel, physician call schedules, quality and error management, review conferences, and termination of primary PCI privileges;

(ii) develop a formal, regularly scheduled (meetings every other month) interventional case review that requires attendance by a critical mass of interventionalists and other physicians, nurses, and technicians who care for primary PCI patients; and

(iii) create a multiple care area group (emergency department, coronary care unit, and cardiac catheterization laboratory) that includes at a minimum the physician and nursing leadership of each care area and meets monthly to review any and all issues related to the primary PCI system, identify problem areas, and develop solutions.

(5) All institutions should design and implement a formal continuing medical education program for staff, particularly in the cardiac catheterization laboratory and coronary care unit.

For hospitals without on-site cardiac surgery programs:

(6) There must be a formal, written agreement with a tertiary institution that provides for unconditional transfer of patients for any required additional care, including emergent or elective cardiac surgery or PCI, for hospitals performing primary PCI without on-site cardiac surgery.

(7) There must be a formal, written agreement with an advanced cardiac life support emergency medical services provider that guarantees arrival of the air or ground ambulance within 30 minutes of a request for patient transport by hospitals performing primary PCI without on-site cardiac surgery.

b. Physician Resources

(1) Physicians who perform primary PCI should meet the ACC/AHA criteria for competency of 75 or more total PCI cases per year.

(2) Physicians newly out of fellowship (less than three years) should have completed a minimum of 50 acute MI's during their fellowship training or 10 proctored cases before being allowed to perform primary PCI alone.

(3) Physicians who perform primary PCI should agree to participate in an on-call schedule.

(4) Physicians who perform primary PCI should meet the credentialing criteria for the institution.

c. Initiation of a New Primary Angioplasty Center Program

(1) The Maryland Health Care Commission should establish an application process to review requests submitted by hospitals seeking approval to provide primary PCI services without on-site cardiac surgery services.

(2) All institutions should demonstrate that they have a minimum of 60-65 and optimally 85-90 acute ST-segment elevation MI's annually.

(3) Because primary PCI is a strategy of care involving a team of health care professionals in multiple care areas, all institutions should begin providing this service only after completing a development program that attends to setting of standards, training of staff, development of logistics and implementation of a formal quality and error management program.[5] The application submitted to the Commission should describe in detail how the hospital proposes to undertake and complete a development program, which may include collaboration with an established primary PCI program. The development program should contain the following major components:

(i) The standards contained in the American College of Cardiology/ American Heart Association Guidelines for Management of Patients with Acute Myocardial Infarction[6] and Guidelines for Percutaneous

[5] Aversano, T, Aversano, LT, Passamani, E, Knatterud, GL, Terrin, ML, Williams, DO, Forman, SA. Thrombolytic therapy vs. primary percutaneous coronary intervention for myocardial infarction in patients presenting to hospitals without on-site cardiac surgery: a randomized controlled trial. *JAMA*, Vol. 287, No. 15, April 17, 2002, Supplement to the 'Methods' Section. Accessed March 20, 2003 at http://www.cport.org/jama.htm.

[6] Ryan TJ, Antman EM, Brooks NH, Califf RM, Hillis LD, Hiratzka LF, Rapaport E, Riegel B, Russell Rom Smith EE III, Weaver WD. ACC/AHA guidelines for the management of patients with acute myocardial infarction: 1999 update: a report of the American College of Cardiology/American Heart

Coronary Intervention[7] will be used to guide care provided in primary PCI programs.

(ii) Nursing and technical staff in both the catheterization laboratory and in pre and post-procedure care units will require additional training, including familiarization with angioplasty equipment, commonly used drugs, intra-aortic balloon counterpulsation equipment, patient transfer to and from the laboratory, and other pre-and post-procedure care issues.

(iii) The logistical issues that need to be addressed in the primary PCI development program include at a minimum: hours of operation, who obtains consent, mechanisms to gather staff, mechanisms to assure availability of staff and catheterization laboratory, plans for recurrent ischemia or infarction, plans to determine the responsible physician during and after primary angioplasty, plans for failed angioplasty, and fall-back plans for primary angioplasty system failure.

(iv) The quality and error management component of the primary angioplasty development program should give special emphasis to minimizing, discovering, reporting, and correcting error in the system of acute MI care.

3. Relationship Between Volume of Primary Angioplasty Procedures and Outcome

Current evidence demonstrates an inverse relationship between the volume of primary angioplasty procedures performed and in-hospital mortality. With respect to the recommended volume of primary PCI cases in hospitals without on-site cardiac surgery, the ACC/AHA guidelines recommend a minimum of 36 procedures per year based on data suggesting that both door to balloon time and in-hospital mortality are significantly lower at hospitals able to perform at this volume level.[8] [9] Assuming that as few as 80 percent of potential cases are taken to the catheterization laboratory as recommended in

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Associatin Task Force on Practice Guidelines (Committee on Management of Acute Myocardial Infarction). www.acc.org. September 1999:1-91.

[7] Smith SC, Jr, Dove JT, Jacobs AK, Kennedy JW, Kereiakes D, Kern MJ, Kuntz RE, Popma JJ, Schaff HV, Williams DO. ACC/AHA Guidelines for Percutaneous Coronary Intervention: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty). *Journal of the American College of Cardiology*. Vol. 37, No. 8, June 15, 2001:1-66.

[8] Smith SC, Jr, Dove JT, Jacobs AK, Kennedy JW, Kereiakes D, Kern MJ, Kuntz RE, Popma JJ, Schaff HV, Williams DO. ACC/AHA Guidelines for Percutaneous Coronary Intervention: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty). *Journal of the American College of Cardiology*. Vol. 37, No. 8, June 15, 2001:21.

[9] Cannon, CP, Gibson, CM, Lambrew CT et al. Relationship of symptom-onset-to-balloon time and door-to-balloon time with mortality in patients undergoing angioplasty for acute myocardial infarction. *JAMA*. 2000; 283:2941-2947.

the earlier discussion regarding Institutional Resources [a.(2)] and adjusting that number to reflect cases likely to undergo primary PCI, an institution would require a minimum of at least 60-65 acute ST-segment elevation MI's annually to ensure that 35-37 primary angioplasty procedures are performed.

Data are also available to suggest that outcomes are better overall for programs performing 49 or more primary PCI cases annually. A study by Magid and colleagues found that high volume primary PCI programs, defined as 49 or more procedures annually, had the lowest mortality when compared to both intermediate and low volume groups.[10] Assuming that as few as 80 percent of potential cases are taken to the catheterization laboratory and adjusting that number for expected actual primary PCI procedures, an institution would require a minimum of 85-90 acute ST-segment elevation MI's annually to ensure an optimal institutional volume of 49-52 primary angioplasty procedures.

Table 1
Relationship Between Annual Acute STEMI Patients and Minimum and Optimal Institutional Volumes of Primary PCI Cases

Relationship Between Annual Acute STEMI Patients and Expected Primary PCI Cases	Minimum Institutional Volume	Optimal Institutional Volume
	Institutions Performing at Least 36 Primary PCI Procedures Annually	Institutions Performing ≥ 49 Primary PCI Procedures Annually
Annual Acute ST-Segment Elevation MI (STEMI) Cases	**60-65**	**85-90**
Expected Primary PCI Cases*	**35-37**	**49-52**

**NOTE: The number of expected primary PCI cases is estimated based on the following assumptions. First, it is assumed that up to 20% of STEMI patients will not undergo primary PCI because of logistical issues that may limit catheterization laboratory availability. Of the potential candidates for primary PCI, it is also assumed that up to 20% will not be suitable for primary PCI (e.g., greater than 12 hrs. from onset to catheterization laboratory arrival). Finally, approximately 10% of eligible patients will not receive a primary PCI intervention because of anatomic and technical considerations.*

While limited data are now available on the relationship between volume of procedures and outcome, the subcommittee believes that under ideal circumstances the benefits of primary PCI are likely best achieved when a minimum of 49 primary PCI cases are performed. A program performing at least 49 cases annually, or approximately one case per week, is more likely to have developed the clinical expertise and operational pathways for timely and effective reperfusion of acutely ill patients. If, however, rapid access to a program doing 49 cases is not available, then a site performing 36 or more cases/year is acceptable. This approach acknowledges important regional differences in access to primary PCI services. The lower volume standard should only be considered in

[10] Magid, DJ, Calonge, BN, Rumsfeld, JS et al. Relation between hospital primary angioplasty volume and mortality for patients with acute MI treated with primary angioplasty vs. thrombolytic therapy. *JAMA*. 2000; 284:3131-3138.

areas of the state where access to a high volume program is not readily available. The optimal and minimum recommended volume guidelines for primary PCI should be reevaluated by the Commission as additional data becomes available on the relationship between volume of procedures and outcome.

4. Patient Groups Suitable for Primary Angioplasty in Settings without On-Site Cardiac Surgery

The Subcommittee on Interventional Cardiology believes that the following types of patients can be considered for emergency PCI in settings without on-site cardiac surgery:

a. ST-segment elevation myocardial infarction (or new LBBB or ST-depression V1-V2 compatible with true posterior infarction) who are:
   - thrombolytic eligible or
   - thrombolytic ineligible.

b. When transfer to a tertiary institution may be harmful for patients with acute myocardial infarction in cardiogenic shock that the treating physician(s) believe, either because the patient is too unstable or because the temporal delay will result in worse outcomes.

c. Patients for whom the primary PCI system was not initially available, who received thrombolytic therapy that subsequently failed. These cases should constitute no more than 10 percent of all cases.

5. Process and Outcome Measures for On-Going Quality Assessment

Monitoring of the outcomes of care for patients presenting with ST-segment elevation MI will facilitate on-going quality improvement efforts and provide the opportunity to measure program compliance, safety, and effectiveness. This requires that a uniform data set be developed, collected, and analyzed from all hospitals in Maryland offering primary PCI services. This data set should build upon the elements collected in the C-PORT project.

The subcommittee believes that a plan should be developed for this effort. Included would be data on: patient demographic and clinical characteristics; times of symptom onset, arrival in the emergency department, arrival in the catheterization lab, catheterization procedure onset and termination, balloon inflation, procedural outcome; complications; need for emergency cardiac surgery; incidence and indication for hospital transfers, adjunctive medical therapies, and clinical outcomes (including in-hospital mortality, stroke, and long-term follow-up).

➢ Elective Percutaneous Coronary Intervention

With the assistance of Maryland cardiologists and cardiac surgeons, the Commission has conducted periodic reviews of the state health planning policy requiring hospitals providing elective PCI services to have on-site cardiac surgery. The charge to the Subcommittee on Interventional Cardiology contained a series of questions regarding elective PCI, including whether current health planning policy should be modified to permit hospitals to perform elective angioplasty without on-site cardiac surgery.

1. Availability of Elective Angioplasty Services

During 2002, the nine Maryland hospitals with open heart surgery and PCI programs performed about 12,000 angioplasty procedures. The Interventional Cardiology Subcommittee found no problem with the availability of elective angioplasty services to Maryland patients.

2. Comparison of Elective Angioplasty Outcomes in Hospitals With and Without On-Site Cardiac Surgery

The current ACC/AHA national guidelines for percutaneous coronary intervention (PCI) recommend that hospitals performing elective PCI have cardiac surgery services available on-site.[11] At institutions without on-site cardiac surgical backup, the ACC/AHA classifies elective angioplasty as Class III[12] meaning there is evidence and/or general agreement that the procedure/treatment is not useful/effective and in some cases may be harmful. Because angioplasty is an evolving technology for treating cardiovascular disease, the ACC/AHA committee has reviewed this policy direction on several occasions over the past 15 years. The current recommendation reaffirming the on-site cardiac surgical backup requirement for elective PCI was completed in March-April 2001 and reflects several important considerations. Those considerations include: the benefit, in terms of better outcomes, of ensuring that high volume interventionalists in high volume programs perform elective PCI; the need for timely management of post-intervention complications; and, the need to ensure the availability of services required for any specialized follow-up care.

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[11] Smith SC, Jr, Dove JT, Jacobs AK, Kennedy JW, Kereiakes D, Kern MJ, Kuntz RE, Popma JJ, Schaff HV, Williams DO. ACC/AHA Guidelines for Percutaneous Coronary Intervention: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty). *Journal of the American College of Cardiology*. Vol. 37, No. 8, June 15, 2001:1-66.

[12] The ACC/AHA uses a classification system to summarize the indications for PCI as follows: *Class I*-conditions for which there is evidence for and/or general agreement that the procedure or treatment is useful and effective; *Class II*-conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment (*Class IIa*-weight of the evidence/opinion is in favor or usefulness/efficacy; *Class IIb*-usefulness/efficacy is less well established by evidence/opinion); and *Class III*-conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective, and in some cases may be harmful.

Over the past two decades, the growing body of experience with angioplasty combined with improvements in the technology, including coronary stents and antiplatelet drugs, has contributed to increasing the clinical success of the procedure and lowering the incidence of complications requiring emergency coronary artery bypass graft (CABG) surgery. Data reviewed by the ACC/AHA in developing the current PCI guidelines shows that the incidence of emergency CABG surgery has declined from 5.8 percent (1977-1986) to between 0.4 -1.3 percent (1995-1998). With improvements in PCI, cardiac surgical backup has changed from having an operating room and surgical team immediately available on a scheduled standby basis to a next available basis.

To date, however, there have been only a few observational studies addressing the safety of elective PCI at hospitals without on-site cardiac surgery. While the limited research conducted has found that it is feasible to perform elective procedures in hospitals without cardiac surgical backup on-site, the small sample of patients studied restricts the extent to which results can reasonably support modifying current planning policies governing the organization of elective PCI services.[13] [14] There has been no clinical trial directly comparing the outcomes of elective PCI performed in hospitals with on-site cardiac surgery with the outcomes of elective PCI performed in hospitals without on-site cardiac surgery. Moreover, methods for identifying those patients who might be best suited for elective PCI in the absence of on-site surgical backup have not been described or validated.

Given the limited body of evidence now available, the Interventional Cardiology Subcommittee believes that Maryland should continue to require that hospitals providing elective angioplasty services have cardiac surgical services on-site. This policy direction, which should continue to be reviewed periodically, should remain in place until clinical evidence confirms the efficacy and safety of elective angioplasty without on-site cardiac surgery backup.

➢ Pilot Project Study on the Need for On-Site Cardiac Surgical Backup for Elective PCI

1. Pilot Project Study to Assess Appropriateness of Modifying Current Policy Regarding Availability of On-Site Cardiac Surgery for Certain Groups of Elective Angioplasty Patients

For cardiac care services, Maryland has developed planning policies based on clinical evidence from medical research and the expertise and advice of cardiologists and cardiac surgeons. For angioplasty services, where significant advances in technology have increased experience with the procedure over the past decade, the Commission has

[13] Klinke, WP and Hui, W. Percutaneous transluminal coronary angioplasty without on-site surgical facilities. *Am J Cardiology*. Vol. 70, December 15, 1992: 1520-1525.
[14] Ting, HH; Garratt, KN; Singh, M et al. Low-risk percutaneous coronary interventions without on-site cardiac surgery: two years' observational experience and followup. *American Heart Journal*. Vol. 145, February 2003:278-284.

supported research designed to examine whether primary angioplasty services can be safely provided by hospitals without on-site cardiac surgery programs. In 1996, the Commission approved a waiver from the requirement for on-site cardiac surgical backup to permit a small number of Maryland hospitals to participate in a research study to evaluate the safety and efficacy of providing primary angioplasty in hospitals without on-site cardiac surgery. The data from this study, the C-PORT clinical trial and registry, made an important contribution to the knowledge base concerning primary angioplasty.

In discussing whether Maryland should support research concerning the need for on-site surgical backup for elective PCI, the Subcommittee on Interventional Cardiology considered a number of issues. While the ability to provide primary angioplasty offered the potential of some clinical benefit to acute MI patients, there is no similar clinical benefit likely with respect to elective cases. On the other hand, the subcommittee recognized the potential benefit to rural hospitals that want to provide primary angioplasty of being able to strengthen program volumes by offering elective procedures. Moreover, the subcommittee recognized the potential value of enhanced convenience for patients, families, and physicians.

Acknowledging there is no clinical benefit for elective patients undergoing angioplasty without on-site surgery, the subcommittee recognizes that the question of the need for on-site cardiac surgical backup for elective angioplasty procedures is the subject of considerable national debate. Given the likelihood that this debate will continue, it is important to consider whether Maryland hospitals should participate in studying the issue given experience with the C-PORT study. Given these considerations, the Interventional Cardiology Subcommittee believes that it would be appropriate for the Maryland Health Care Commission to consider supporting a waiver for a well-designed, peer reviewed research proposal to study the safety of elective PCI without on-site cardiac surgery. This research proposal must be capable of answering questions regarding the need for on-site cardiac surgical backup for elective PCI using accepted principles of scientific investigation. Hospitals wishing to participate in this research proposal could apply to the Commission for this waiver.

2. Considerations Regarding the Design and Implementation of an Elective PCI Pilot Project Study

The Interventional Cardiology Subcommittee believes that a research proposal to study elective PCI without on-site cardiac surgery must, at a minimum, include the following components: (1) detailed description of the research design and methods; (2) protocol for including patients in the elective PCI research study; (3) need for institutional review board review; (4) criteria for participating hospital sites and physicians (including minimum volume standards for the practitioner and institution); (5) data collection and management plan; (6) timetable for initiating and completing the study; and (7) source and amount of funding necessary to conduct the research study. The subcommittee also recommends that the Maryland Health Care Commission appoint an advisory committee to review and provide advice on any research proposal submitted to the Commission to study elective angioplasty without on-site cardiac surgery backup. In

addition, the Commission should establish an advisory committee to assist in interpreting the results of this and/or other research on the safety of elective PCI without on-site cardiac surgery and to advise the Commission on the appropriateness of modifying State health planning policy governing the requirement to have cardiac surgical services on-site for elective angioplasty. The subcommittee also recommends that the Commission analyze the system impact, including access, cost, and quality implications, of elective angioplasty being performed in hospitals without on-site cardiac surgery.

➢ Volume –Quality Relationship for Elective Angioplasty

Under the current *Maryland State Health Plan: Specialized Health Care Services-Cardiac Surgery and Therapeutic Catheterization Services,* the minimum volume threshold for angioplasty is 200 procedures annually. This recommendation is based on the minimum volume guidelines published by the ACC/AHA for coronary angioplasty programs in 1993.[15] The recently updated ACC/AHA national guidelines recommend a minimum institutional volume of 200 to 400 procedures annually and an optimal institutional volume of more than 400 procedures annually (Refer to Table 2). Those current guidelines recommend that PCI procedures be performed by higher volume operators (≥ 75 cases annually) with advanced technical skills (e.g., subspecialty certification) at well-equipped institutions with experienced support staff performing at least 400 procedures annually.[16]

Between 1993-2000, nine major studies, using data sources ranging from registries to hospital discharge files, have examined the relationship between the volume of coronary angioplasty procedures and outcome. The outcome measures used by these studies include CABG surgery following a failed angioplasty procedure and/or death. Table 3 summarizes the characteristics and findings of each study. All nine of these studies suggest that hospitals performing higher volumes of coronary angioplasty procedures have fewer complications and/or deaths than low volume hospitals. The results from six of the studies indicate that the appropriate minimum volume benchmark for PCI programs is 400 cases annually. One study, reflecting the experience from New York State, suggests that 600 cases annually should serve as the minimum volume standard for hospital angioplasty programs. While many of the studies were done before the widespread use of stents, the study by McGrath and colleagues examined the relationship between physician and hospital PCI volumes and patient outcomes after stents became routinely used in PCI cases. This study shows that the strong inverse relationship between volume and patient outcomes (i.e., most favorable outcomes were observed at the highest volume centers with the highest volume physicians), as measured

[15] Ryan, TJ. Bauman WB. Kennedy JW. et al. Guidelines for Percutaneous Transluminal Coronary Angioplasty: A Report of the American Heart Association/American College of Cardiology Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures. *Circulation*. 1993; 88:2987-3007.
[16] Smith SC, Jr, Dove JT, Jacobs AK, Kennedy JW, Kereiakes D, Kern MJ, Kuntz RE, Popma JJ, Schaff HV, Williams DO. ACC/AHA Guidelines for Percutaneous Coronary Intervention: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty). *Journal of the American College of Cardiology*. Vol. 37, No. 8, June 15, 2001:1-66.

by mortality, remains even with recent advances in stent technology that have reduced complications and mortality following PCI.[17]

Table 2
Recommendations for PCI Institutional and Operator Volume at Centers with On-Site Cardiac Surgery

Operator Volume	Minimum Institutional Volume	Optimal Institutional Volume
	Institutions Performing 200-400 Procedures Annually	**Institutions Performing > 400 Procedures Annually**
Low (< 75 procedures annually)	**Class IIb** PCI done by low volume operators (< 75) at low volume centers (200-400)* *(Level of Evidence:C)* *Note: An institution with a volume < 200 procedures/year, unless in a region that is underserved because of geography, should carefully consider whether it should continue to offer the service.*	**Class IIa** PCI done by low volume operators (< 75) at high volume centers (> 400)* *(Level of Evidence: C)* *Note: Ideally, operators with annual procedure volume < 75 should only work at institutions with an activity level of > 600 procedures/year.*
Acceptable (≥ 75 procedures annually)	**Class IIa** PCI done by operators with acceptable volume (≥ 75) at low volume centers (200-400) *(Level of Evidence: C)*	**Class I** PCI done by operators with acceptable volume (≥ 75) at high volume centers (> 400) *(Level of Evidence: B)*

*Note: Operators who perform <75 procedures/year should develop a defined mentoring relationship with a highly experienced operator who has an annual procedural volume ≥ 150 procedures/year. (For definitions of the ACC/AHA classes refer to Footnote 12 in this document. The weight of evidence in support of the recommendation is as follows: *Level of Evidence A:* Data derived from multiple randomized clinical trials; *Level of Evidence B*: Data derived from a single randomized trial or nonrandomized studies; *Level of Evidence C*: Consensus opinion of experts)

Source: Smith SC, Jr, Dove JT, Jacobs AK, Kennedy JW, Kereiakes D, Kern MJ, Kuntz RE, Popma JJ, Schaff HV, Williams DO. ACC/AHA Guidelines for Percutaneous Coronary Intervention: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty). *Journal of the American College of Cardiology*. Vol. 37, No. 8, June 15, 2001:20.

In summary, the Interventional Cardiology Subcommittee concludes that available data clearly documents the relationship between major complications and annual volume of procedures for elective PCI. Higher volume PCI programs have been shown to experience lower mortality rates and lower risk of emergency CABG surgery. Given these findings, the subcommittee believes that PCI programs should perform a minimum of 200-400 procedures annually. Consistent with ACC/AHA recommendations, the subcommittee concludes that for optimal patient outcome an institutional volume of more than 400 PCI procedures should be performed annually.

[17]McGrath, PD; Wennberg, DE; Dickens, JD; Siewers, AE; Lucas, FL; Malenka, DJ; Malenka, DJ; Kellett, MA; Ryan, TJ. Relation between operator and hospital volume and outcomes following percutaneous coronary interventions in the era of the coronary stent. *JAMA*. Volume 284, No.24. December 27, 2000: 3139-3144.

Table 3
Findings of Major Studies on the Relationship Between Coronary Angioplasty Program Volumes and Outcomes

Study	Data Source	Year(s) of Data/Total Sample Size	Findings
McGrath, PD; Wennberg, DE; Dickens, JD; Siewers, AE; Lucas, FL; Malenka, DJ; Malenka, DJ; Kellett, MA; Ryan, TJ. Relation between operator and hospital volume and outcomes following percutaneous coronary interventions in the era of the coronary stent. *JAMA*. Volume 284, No.24, December 27, 2000: 3139-3144.	Medicare National Claims History files- Part A (hospital) and Part B (physician) for each hospitalization billed to Medicare	1997 N= 167,208 (1,003 hospitals; 6,534 physicians)	Overall unadjusted rates of CABG during the index hospitalization and 30-day mortality were 1.87% and 3.30%, respectively. After adjustment for case mix, patients treated by low-volume (< 30 Medicare procedures) physicians had an increased risk of CABG vs. patients treated by high-volume (>60 Medicare procedures) physicians (2.25% vs. 1.55%; P<.001), but there was no difference in 30-day mortality rates (3.25% vs. 3.39%; P<.27). Patients treated at low volume (<80 Medicare procedures) centers had an increased risk of 30-day mortality vs. patients treated at high-volume (>160 Medicare procedures) centers (4.29% vs. 3.15%; P<.001), but there was no difference in risk of CABG. In patients who received coronary stents, the CABG rate was 1.20% vs. 2.78% for patients not receiving stents, and the 30-day mortality rate was 2.83% vs. 3.94%. Among patients who received stents, those treated at low-volume centers had an increased risk of 30-day mortality vs. those treated at high-volume centers, whereas those treated by low volume physicians had an increased risk of CABG vs. those treated by high volume physicians.
Richie, JL; Maynard, C; Chapko, MK; et al. Association between percutaneous transluminal coronary angioplasty volumes and outcomes in the health care cost and utilization project 1993-1994. *AmJ Cardiology*. Volume 831, No. 4, February 15, 1999: 493-7.	Nationwide Inpatient Sample from HCUP (20 percent stratified sample of acute care, non-federal hospitals in 17 states)	1993-1994 N = 163,527 (214 hospitals)	Hospital volumes defined as low (< 200 cases per year), medium (201-400), and high (> 400). For both AMI and non-AMI groups, rates of adverse outcomes (defined as same admission surgery and hospital mortality) were lower in high-volume institutions after risk adjustment.
McGrath, PD; Wennberg, DE; Malenka, DJ; Kellett, MA et al. Operator volume and outcomes in 12,988 percutaneous coronary interventions. *JACC*. Volume 31, No. 3, March 1, 1998: 570-576.	Northern New England Cardiovascular Disease Study Group	1990-1993 N=12,988 (5 hospitals; 31 primary operators)	After adjustment for case-mix, higher angiographic and clinical success rates, with fewer referrals to CABG, were seen as operator volume increased. There was a trend toward higher MI rates for high volume operators; all terciles had similar in-hospital mortality rates. There is a significant relation between operator volume and outcomes in PCIs.
Hannon, EL; Racz, M; Ryan, TJ et al. Coronary angioplasty volume – outcome relationships for hospitals and cardiologists. *JAMA*. Vol. 227, No. 11, March 19, 1997: 892-898	Coronary Angioplasty Reporting System of the New York Department of Health	1991-1994 N = 62,670 (31 hospitals)	Patients undergoing angioplasty in hospitals with annual volumes less than 600 experienced a significantly higher risk-adjusted in-hospital mortality rate and risk-adjusted same stay CABG surgery rate.

Study	Data Source	Year(s) of Data/Total Sample Size	Findings
Kimmel, SE; Berlin, JA; Laskey, WK. The relationship between coronary angioplasty procedure volume and major complications. *JAMA*. Volume 274, No. 14, October 11, 1995:1137-1142.	Registries of the Society for Cardiac Angiography and Interventions	1992 – 1993 N = 19,594 (48 centers)	Risk of major complications for labs performing 400-599 procedures per year was significantly lower than that for labs performing fewer than 200 procedures per year and for labs performing 200-399 procedures per year. No significant difference in major complications between the highest volume labs (600+) and labs performing 400-599 procedures per year.
Jollis, JG; Peterson, ED; et al. Relationship between physician and hospital coronary angioplasty volume and outcome in elderly patients. *Circulation*. Vol. 95, No. 11, June 3, 1997: 2485-2491.	Medicare National Claims History File (Part A and B claims)	1992 N = 97,478 (984 hospitals)	After risk adjustment, hospital volume was inversely associated with both in-hospital death and combined end point of in-hospital bypass surgery or death, with improving outcomes seen up to 200 annual Medicare cases. This inflection point is consistent with an overall annual volume of 400 to 600 cases per year.
Jollis, JG; Peterson, ED; Delong, ER et al. The relation between the volume of coronary angioplasty procedures at hospitals treating Medicare beneficiaries and short-term mortality. *NEJM*. Vol. 331, No. 24, December 15, 1994: 1625-1629.	Medicare Provider Analysis and Review (MEDPAR) file from HCFA for hospitalized Medicare enrollees	1987-1990 N = 217,836 (1,194 hospitals)	Higher rates of mortality and CABG observed in all groups of patients treated in hospitals that performed fewer than 100 angioplasty procedures per year on Medicare beneficiaries (this volume can be extrapolated to an overall annual volume of 200 to 400 angioplasty procedures).
Richie, JL; Phillips, KA; Luft, HS. Coronary angioplasty: statewide experience in California. *Circulation*. Vol. 88, No. 6, December 1993: 2735-2743	California Hospital Discharge Data Base	1989 N = 24,883 (110 hospitals)	For both AMI and non-AMI groups, likelihood of having either CABG and/or death was significantly increased at lower volume institutions (< 200) when compared with institutions performing 200 – 400 and greater than 400 cases
Phillips, KA; Luft, HS; Richie, JL. The association of hospital volumes of percutaneous transluminal coronary angioplasty with adverse outcomes, length of stay, and charges in California. *Medical Care*. Vol. 33, No. 5, 1995: 502-514	California Hospital Discharge Data Base	1989 N = 24,856 (110 hospitals)	Rates of adverse outcomes (defined as CABG surgery after PTC and/or in-hospital mortality) were significantly higher than expected in low volume hospitals (<201) and significantly lower than expected in high volume hospitals. (>400).

Steering Committee Review and Endorsement

The Steering Committee of the Advisory Committee on Outcome Assessment in Cardiovascular Care reviewed the findings and recommendations of the Interventional Cardiology Subcommittee at their April 14, 2003 and June 2, 2003 meetings. At the June 2, 2003 meeting, the Steering Committee endorsed the findings and recommendations of the Interventional Cardiology Subcommittee regarding acute ST-segment elevation myocardial infarction with the suggestion that the Commission consider using the metrics outlined in the requirements for primary PCI programs (Appendix C) as potential data elements for the acute care hospital report card. The Steering Committee further recommended that the Commission review and evaluate the recommendations regarding primary PCI on at least a yearly basis to ensure that as research and knowledge change (e.g., maximum door-to-balloon times, minimum volume requirements) the recommendations remain current.

At the June 2, 2003 meeting, the Steering Committee also endorsed the findings and recommendations of the Interventional Cardiology Subcommittee regarding elective angioplasty with dissenting opinions submitted by two members. The dissenting opinions submitted by Mark Midei, M.D. and Donald Dembo, M.D. are provided in Appendix B. In its review of the process recommended by the subcommittee for considering a research proposal to study the safety of elective angioplasty in hospitals without on-site cardiac surgery backup, the Steering Committee suggested that the specifications include consideration of the need for an adequate control group and power analysis to determine the appropriate number of participants in the research study.

Appendix A
Brief Biographies for Steering Committee Members

Advisory Committee on Outcome Assessment in Cardiovascular Care

Brief Biographies of Steering Committee Members

Robert R. Bass, M.D. is Executive Director of the Maryland Institute for Emergency Medical Services Systems. Dr. Bass received his Medical Degree from the University of North Carolina at Chapel Hill. He completed his internship at the U.S. Naval Hospital in Portsmouth, Virginia and a residency in family medicine at the U.S. Naval Hospital in Charleston, South Carolina. Dr. Bass is President-elect of the Board of Directors of the National Association of EMS Physicians, a member of the Board of Directors of the American Trauma Society, Chairman of the EMS Committee of the American College of Emergency Physicians, and a member of the Trauma Systems Vision Committee of the National Highway and Traffic Administration. Dr. Baumgartner has authored numerous scientific papers published in journals such as the *Journal of Thoracic Cardiovascular Surgery, Circulation, Journal of Heart Transplant, and Annals of Thoracic Surgery.* He is a member of the Advisory Committee's Subcommittee on Interventional Cardiology.

William A. Baumgartner, M.D. is Cardiac Surgeon-in-Charge and the Vincent L. Gott Professor of Surgery at Johns Hopkins Medical Institutions. Dr. Baumgartner serves as the Vice Dean of Clinical Affairs and President of the Clinical Practice Association. He received his medical degree from the University of Kentucky Medical School. Dr. Baumgartner completed his general surgery and cardiothoracic surgery training at Stanford University Medical School in Stanford, California. His clinical interests include adult cardiac surgery, valvular heart surgery, and cardiac transplantation. Dr. Baumgartner has authored numerous scientific papers published in journals such as the *Journal of Thoracic Cardiovascular Surgery, Circulation, Journal of Heart Transplant, and Annals of Thoracic Surgery.* He is a member of the Advisory Committee's Subcommittee on Quality Measurement and Data Reporting.

Luther T. Clark, M.D. is Chief of the Division of Cardiovascular Medicine and Director of the Cardiology Fellowship Training Program at SUNY-Health Science Center at Brooklyn in New York. He received his Medical Degree from Harvard Medical School. Dr. Clark completed his internship and residency in internal medicine and cardiology fellowship at The Roosevelt Hospital (now the St. Luke-Roosevelt Hospital Center) in New York City. His current appointments include: Chairman of the African American Lipid Council; member of the New York State Cardiac Advisory Committee; Chairman of the Awards Committee of the New York State Chapter of the American College of Cardiology; and member of the Executive Board of the New York Cardiological Society. Dr. Clark has authored numerous scientific papers published in journals such as the *Journal of the Association of Academic Minority Physicians, Circulation, The American Journal of Medicine, and Annals of Internal Medicine.*

Donald H. Dembo, M.D. is Medical Director for Johns Hopkins Cardiology at Timonium. He received his Medical Degree from the University of Maryland School of Medicine. Dr. Dembo completed his internship at Sinai Hospital and residency at the University of Maryland Hospital in Baltimore, Maryland. He served as a Research Fellow in cardiology at the American Heart Association, Maryland affiliate. Dr. Dembo is Assistant Professor of Medicine at The Johns Hopkins School of Medicine and Governor for Maryland of the American College of Cardiology. He is the past President of the Medical and Chirurgical Faculty of Maryland and the Baltimore City Medical Society. He is a member of the Advisory Committee's Subcommittee on Long Term Issues.

James L. Field, D.B.A. is Executive Director of The Advisory Board Company. Located in Washington, D.C., the Advisory Board conducts research for a large membership of hospitals, health systems, device manufacturers, pharmaceutical companies, and payers. Dr. Field's areas of expertise include clinical best practices, new technologies and procedures, finances of patient care, managed care contracting, and hospital/group practice strategy. He holds Master of Business Administration and Doctor of Business Administration degrees from Harvard Business School. Dr. Field has held research fellowships with the U.S. General Accounting Office, Harvard University (Center for Business and Government, Kennedy School of Government), and Harvard Business School. He is a member of the Advisory Committee's Subcommittee on Interventional Cardiology.

Scott D. Friedman, M.D. practices at the Chesapeake Cardiology Clinic in Easton, Maryland. Dr. Friedman is on the active medical staff at Easton Memorial Hospital where has served as the Chairman of the Department of Medicine and Director of the Cardiac Catheterization Laboratory. Dr. Friedman received his Doctor of Medicine degree from the University of Maryland School of Medicine and served his internship and residency at the University of Maryland Hospital in Baltimore, Maryland. He completed his fellowship in cardiology at the Boston City Hospital/University Hospital in Boston, Massachusetts. Dr. Friedman serves on the Board of Managers for the Shore IPA and the Board of Trustees for the Shore MSO. He is a member of the Advisory Committee's Subcommittee on Interventional Cardiology.

Bartley P. Griffith, M.D. is a Professor of Surgery, Chief of the Division of Cardiac Surgery, and Director of Cardiopulmonary Transplantation at the University of Maryland School of Medicine. He also serves as the Director of the Cardiothoracic Residency Program for the University of Maryland School of Medicine. Dr. Griffith received his Medical Degree from Jefferson Medical College in Philadelphia, Pennsylvania. He completed an internship in surgery and residency and research fellowship in general and cardiothoracic surgery at the University of Pittsburgh School of Medicine. Dr. Griffith has authored numerous scientific papers published in journals such as the *Journal of Thoracic Cardiovascular Surgery, Transplant Proceedings, and Journal of Heart Lung Transplant.* He has served as Chairman of the Research Committee of The Thoracic Surgery Foundation for Research and Education and as a member of the Advisory Committee on Organ Transplantation of the U.S. Department of Health and Human Services. Dr. Griffith is a member of the Advisory Committee's Subcommittee on Interventional Cardiology.

Jeffrey D. Jones, M.D., a cardiologist, chairs the Advisory Committee's Subcommittee on Inter-Hospital Transport. Since 1994, Dr. Jones has been on the staff of Washington County Hospital in Hagerstown, Maryland. He currently practices with Hagerstown Heart, P.A. Other current appointments include the Food and Drug Administration's Cardiovascular Devices Advisory Panel. Dr. Jones is a former member of the National Institutes of Health (NIH) Steering Committee for the Antiarrhythmic versus Implantable Defibrillator Study and the NIH National Heart Attack Alert Program Coordinating Committee. Dr. Jones received his Doctor of Medicine degree from the University of Maryland and served his internship and residency in internal medicine at Washington Hospital Center in Washington, D.C. He completed fellowships in cardiology at the University of South Florida and the Washington Hospital Center.

Steve B. Lowenthal, M.D. is the Executive Vice President and Chief Medical Officer for St. Agnes Healthcare in Baltimore, Maryland. Prior to joining St. Agnes Healthcare, Dr. Lowenthal was the Senior Vice President for Medical Affairs and Chief Medical Officer at Holy Family Center in Des Plaines, Illinois and an Associate Dean at Rush Medical College in Chicago, Illinois. Dr. Lowenthal received his Doctor of Medicine degree from the University of Health Sciences/Chicago Medical School and served his internship in general surgery at Lenox Hill Hospital in New York City, NY. He completed his residency at the Los Angeles County/USC Medical Center in urology. Dr. Lowenthal also holds a Master of Public Health Degree from the Medical College of Wisconsin with a concentration in health services administration. He is a member of the Advisory Committee's Subcommittee on Interventional Cardiology.

Thom A. Mayer, M.D. is President and Chief Executive Officer of Emergency Physicians of Northern Virginia, Ltd. Dr. Mayer is a founding member and President-elect of the Society for Pediatric Emergency Medicine. Through 2002, Dr. Mayer served as Chairman of the Department of Emergency Medicine at Inova Fairfax Hospital, Director of Flight Services for Inova Medical AirCare, and EMS Medical Director for the Fairfax County Fire and Rescue Department. His academic appointments include Professor of Emergency Medicine and Pediatrics at Georgetown University School of Medicine, Professor of Emergency Medicine at George Washington University School of Medicine, and Clinical Professor of Pediatrics at the University of Virginia Health Sciences Center. Dr. Mayer received his medical degree from Duke University School of Medicine. He completed pediatric and surgical residencies at the University of Utah and a research fellowship in pediatric surgery at Primary Children's Medical Center. He is a member of the Advisory Committee's Subcommittee on Inter-Hospital Transport.

Mark G. Midei, M.D. is Director of the Cardiac Catheterization Laboratory at St. Joseph Medical Center in Baltimore, Maryland and Assistant Professor of Medicine in the Division of Cardiology at The Johns Hopkins University School of Medicine. Dr. Midei received his Doctor of Medicine degree from Northeastern Ohio Universities College of Medicine. He completed his internship, residency, and cardiology fellowship at The Johns Hopkins Hospital. Dr. Midei has contributed to more than 50 publications published in journals that include *Circulation* and the *American Journal of Cardiology*. Dr. Midei is a member of the Baltimore City Medical Society, the Maryland Society of Cardiology, and North American Society of Pacing and

Electrophysiology. He is a member of the Advisory Committee's Subcommittee on Interventional Cardiology.

Luis Mispireta, M.D. chairs the Quality Measurement and Data Reporting Subcommittee of the Advisory Committee. Since 1994, he has served as Chief of the Division of Cardiac Surgery at Union Memorial Hospital in Baltimore, Maryland. He also serves as Chairman of the Cardiovascular Performance Improvement Committee at Union Memorial Hospital and is the Medical Director of Cardiac Services for the Western Maryland Health System in Cumberland, Maryland. Other current appointments include Chairman of the Thoracic and Cardiovascular subsection of the District of Columbia Medical Society. Dr. Mispireta received his Doctor of Medicine degree from Cayetano Heredia University, Rimac in Lima, Peru. He served his internship and residency in general surgery at the Washington Hospital Center and fellowships in cardiothoracic surgery at George Washington University Hospital, Children's Hospital, and the Washington Hospital Center in Washington, D.C.

Hilary T. O'Herlihy, M.D. is President of the Medical and Chirurgical Faculty for the State of Maryland. He received his Medical Degree from the National University of Ireland, Cork, Ireland. Dr. O'Herlihy completed his internship at St. Mary's Hospital in Philadelphia, Pennsylvania and residencies at Union Memorial Hospital in Baltimore, Maryland and University of Saskatchewan, Saskatoon, Canada. He served fellowships at Johns Hopkins Hospital and Women's Hospital in Baltimore, Maryland. Dr. O'Herlihy is an Assistant Professor of Medicine at Johns Hopkins University and the past Chairman of the North Arundel Hospital Foundation. He has also served as the past president of the Maryland Affiliate Chapter of the American Heart Association and Maryland Society of Cardiology. He is a member of the Advisory Committee's Subcommittee on Quality Measurement and Data Reporting.

Eugene R. Passamani, M.D., Director for Cardiology and Medical Education at Suburban Hospital in Bethesda, Maryland, chairs the Advisory Committee's Long Term Issues Subcommittee. Effective January 2000, Dr. Passamani was elected to the Corporate Office of Vice President, Quality for Suburban Hospital. Other current appointments include the Publications Committee, Task Force on Clinical Data Standards, and Database Research and Development Committee of the American College of Cardiology; President-Elect, Mid-Atlantic Affiliate, American Heart Association; and Member, Women's Health Initiative Working Group at the National Heart, Lung, and Blood Institute. Dr. Passamani received his Doctor of Medicine degree from from University of Michigan Medical School. He received postgraduate training in medicine as an intern at the Massachusetts General Hospital and completed his residency and cardiology fellowship at Washington University's Barnes Hospital in St. Louis, Missouri.

Nelson J. Sabatini, Secretary of the Maryland Department of Health and Mental Hygiene, serves as an ex-officio member of the Steering Committee. Prior to his appointment by Governor Robert L. Ehrlich, Jr., Mr. Sabatini served as Executive Vice President of the University of Maryland Medical System. Sabatini also served as Secretary of Health and Mental Hygiene during the Schaefer Administration. After leaving state government in 1995, he became Vice President of Integrated Delivery System Operations for the University of Maryland Medical System. He was promoted to the Senior Vice President of Delivery Systems and Network Development in 1998, and in 1999 to his most recent position, Executive Vice President for

Community Hospital Integration and Network Development. He has also held various positions in the Social Security Administration and the U.S. Department of Health and Human Services at the federal level. Sabatini earned a B.A. Degree from Lewis College in Illinois. He has received numerous awards from civic and community organizations.

James Scheuer, M.D., Professor of Medicine and University Chairman Emeritus at the Albert Einstein College of Medicine/Montefiore Medical Center in New York, chairs the Steering Committee. Dr. Scheuer received his medical degree from Yale University Medical School. He served his internship at Bellevue Hospital in New York and his residency at Mount Sinai Hospital, also in New York. Dr. Scheuer trained as a National Institutes of Health postdoctoral fellow at New York Hospital, Cornell Medical Center. He is the past president of the New York Cardiological Society and has served on the editorial boards of many medical journals, including *Cardiology*, *Circulation Research*, *Circulation*, and the *American Journal of Cardiology*.

Sidney C. Smith, Jr., M.D. is Director of the Center for Cardiovascular Science and Medicine and Professor and Chief of Cardiology at University of North Carolina Health Care in Chapel Hill, North Carolina. Dr. Smith chairs the American College of Cardiology/American Heart Association (AHA) Committee on Guidelines for Percutaneous Coronary Intervention. Other appointments include Chief Science Officer for the AHA National Office, Executive Board of the World Heart Federation, Chairman of the World Heart Forum, Member of the Get with the Guidelines Science Subcommittee of the AHA. He serves on the New York State Cardiac Advisory Committee Workgroup on Angioplasty in Non-Surgery Hospitals. His special interests include interventional cardiology, coronary angioplasty, valvular heart disease, and preventive cardiology. Dr. Smith received his Medical Degree from Yale Medical School and served an internship and residency in internal medicine at Peter Bent Brigham Hospital in Boston, Massachusetts. Dr. Smith also completed his fellowship in cardiology at Peter Bent Brigham Hospital. He is a member of the Advisory Committee's Subcommittee on Interventional Cardiology.

David O. Williams, M.D. chairs the Interventional Cardiology Subcommittee of the Advisory Committee. Dr. Williams is Director of the Cardiovascular Laboratory and Interventional Cardiology at Rhode Island Hospital in Providence, Rhode Island. He is a Professor of Medicine at the Brown University School of Medicine and a Member of the Cardiac Care Advisory Committee for the Rhode Island State Department of Health. Dr. Williams served on the American College of Cardiology/American Heart Association Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty. Other current appointments include the Executive and Steering Committees of the Registry for Percutaneous Transluminal Coronary Angioplasty and the Balloon Valvuloplasty Registry of the National Heart, Lung, and Blood Institute; Interventional Cardiology Test Committee of the American Board of Internal Medicine; and Chair of the Cardiac Catheterization Committee of the American College of Cardiology. Dr. Williams received his Doctor of Medicine degree from Hahnemann Medical College and served his internship and residency in internal medicine at Hahnemann Hospital in Philadelphia, Pennsylvania. He completed his fellowship in cardiology at the University of California School of Medicine in Davis, California.

Appendix B
Dissenting Opinions from Steering Committee Members Regarding Recommendations on Interventional Cardiology

Dissenting Opinions from Steering Committee Members Regarding Recommendations on Interventional Cardiology

- **Dissenting Opinion Submitted by Donald H. Dembo, M.D.**

You recall my reservations regarding elective PTCA without surgical backup. The mission of MHCC is to assure access, preserve quality and control costs. Opening PTCA would clearly dilute the number of cases at tertiary centers potentially affecting quality. It is well recognized that outcome, including mortality, myocardial infarction and other quality of life issues are related inversely to the number of cases performed in a given institution. Certainly expense would increase with duplication of equipment and dilution of the acknowledged shortage of skilled paraphysician personnel (technicians and nurses). The concept of reserving non-backup patients to those at low risk is fanciful. There is no way to predict complications requiring surgical backup. This addresses the litigious environment. It should take a brave cardiologist to provide this service. Finally, why? We do not have an access problem in this state. Convenience as a reason for PTCA anywhere pales in comparison to the mission of cost, quality, and access which we presently fulfill proudly.

Donald H. Dembo, M.D.
President, Maryland Chapter of the American College of Cardiology
Johns Hopkins Cardiology at Timonium
Baltimore, Maryland

- **Dissenting Opinion Submitted by Mark G. Midei, M.D.**

Thank you for the opportunity to express my dissenting opinion regarding the Commission's consideration of elective PCI in non-surgical hospitals.

As you are aware, the current standard of care couples elective PCI with hospitals capable of providing emergency surgical backup. While there are many side benefits to this concentration of resources and expertise, the chief reason for this coupling is the infrequent need, but certain benefit of immediate cardiac surgery in some patients undergoing PCI. While certain anatomic and clinical characteristics increase the likelihood of complication, arterial injury requiring emergency surgery remains unpredictable—no patient can be considered "no risk."

As a member of the Interventional Subcommittee, I can attest to the lively debate over the topic of elective PCI in non-surgical hospitals. The committee was very clear that the very best that any "study" could achieve was equivalent quality to existing programs, and that the chief benefit to patients would be added convenience—patients admitted to a non-surgical hospital would no longer require transfer to another facility for PCI.

I am opposed to the provision of elective PCI in non-surgical hospitals as proposed in the Committee's report. Although one runs the risk of being labeled anti-intellectual in opposing the "study" of anything, the Committee document lacks sufficient guidance as to what constitutes a "

study" while allowing for an elevation of patient risk. Dr. Williams has repeatedly stated that any "study" would require that patient safety be assured, but , of course, when equivalence to existing program safety is the goal, patient safety is the actual variable being tested.

Any effort to provide PCI at non-surgical hospitals does come with some societal cost. The concentration of resources and expertise in the Maryland model leads to better quality at lower cost. The occurrence of a complication outside of the current standard of care raises a legitimate question of liability whether or not cause and effect can be proven.

The waiver granted to hospitals participating in C-PORT took creative thinking on the part of the Commission, and the action is to be lauded. I believed in C-PORT when it was conceived, I have committed my patients to the study, and I continue to participate. Patients willing to risk enrollment in C-PORT were rewarded with a clear clinical benefit which was anticipated and defined before the Commission chose to act. Patients undergoing elective PCI in non-surgical hospitals will face risk with no defined clinical benefit. For the Commission to allow this, even under the guise of a study, will result in injury to our patients.

Mark G. Midei, M.D., FACC
Mid-Atlantic Cardiovascular Associates
Baltimore, Maryland

APPENDIX C

Summary of Recommended Requirements for Primary PCI Programs: Hospitals with and without On-Site Cardiac Surgery

Table C-1
Summary of Recommended Requirements for Primary PCI Programs: Hospitals with and without On-Site Cardiac Surgery

Category	Recommended Requirement for Primary PCI Program	Hospitals with On-Site Cardiac Surgery	Hospitals without On-Site Cardiac Surgery
Institutional Resources	1) All institutions should provide primary PCI as routine, treatment of choice for all appropriate AMI patients 24 hours per day, seven days per week.	**Yes**	**Yes**
	2) All institutions should provide primary PCI as soon as possible and not to exceed 120 minutes from patient arrival (i.e., door-to-balloon time of ≤ 120 minutes) for 80 percent of appropriate patients.	**Yes**	**Yes**
	3) All institutions should have adequate physician, nursing, and technical staff to provide cardiac catheterization laboratory and coronary care unit services to acute MI patients 24 hours per day, seven days per week.	**Yes**	**Yes**
	4) All institutions should have a written commitment by hospital administration signed by the hospital president to support the program, and be required to:	**Yes**	**Yes**
	i) identify a physician director of interventional cardiology services responsible for defining and implementing credentialing criteria for the catheterization laboratory and for overall primary PCI program management, including responsibility for equipment, personnel, physician call schedules, quality and error management, review conferences, and termination of primary PCI privileges;	**Yes**	**Yes**
	ii) develop a formal, regularly scheduled (meetings every other month) interventional case review that requires attendance by a critical mass of interventionalists and other physicians, nurses, and technicians who care for primary PCI patients; and	**Yes**	**Yes**
	iii) create a multiple care area group (emergency department, coronary care unit, and cardiac catheterization laboratory) that includes at a minimum the physician and nursing leadership of each care area and meets monthly to review any and all issues related to the primary PCI system, identify problem areas, and develop solutions.	**Yes**	**Yes**
	5) All institutions should design and implement a formal continuing medical education program for staff, particularly in the cardiac catheterization laboratory and coronary care unit.	**Yes**	**Yes**

Category	Recommended Requirement for Primary PCI Program	Hospitals with On-Site Cardiac Surgery	Hospitals without On-Site Cardiac Surgery
Institutional Resources (Continued)	6) There must be a formal, written agreement with a tertiary institution that provides for unconditional transfer of patients for any required additional care, including emergent or elective cardiac surgery or PCI, for hospitals performing primary PCI without on-site cardiac surgery.	**Not Applicable**	**Yes**
	7) There must be a formal, written agreement with an advanced cardiac life support emergency medical services provider that guarantees arrival of the air or ground ambulance within 30 minutes of a request for patient transport by hospitals performing primary PCI without on-site cardiac surgery.	**Not Applicable**	**Yes**
Physician Resources	1) Physicians who perform primary PCI should meet the ACC/AHA criteria for competency of 75 or more total PCI cases per year.	**Yes**	**Yes**
	2) Physicians newly out of fellowship (less than three years) should have completed a minimum of 50 acute MI's during their fellowship training or 10 proctored cases before being allowed to perform primary PCI alone.	**Yes**	**Yes**
	3) Physicians who perform primary PCI should agree to participate in an on-call schedule.	**Yes**	**Yes**
	4) Physicians who perform primary PCI should meet the credentialing criteria for the institution.	**Yes**	**Yes**
Initiation of New Primary Angioplasty Center Program	1) The Maryland Health Care Commission should establish an application process to review requests submitted by hospitals seeking approval to provide primary PCI services without on-site cardiac surgery services.	**Not Applicable**	**Yes**
	2) All institutions should demonstrate that they have a minimum of 60-65 and optimally 85-90 acute ST-segment elevation MI's annually.	**Yes**	**Yes**

Category	Recommended Requirement for Primary PCI Program	Hospitals with On-Site Cardiac Surgery	Hospitals without On-Site Cardiac Surgery
Initiation of New Primary Angioplasty Center Program (Continued)	3) Because primary PCI is a strategy of care involving a team of health care professionals in multiple care areas, all institutions should begin providing this service only after completing a development program that attends to setting of standards, training of staff, development of logistics and implementation of a formal quality and error management program. The application submitted to the Commission should describe in detail how the hospital proposes to undertake and complete a development program, which may include collaboration with an established primary PCI program. The development program should contain the following major components:		
	i) The standards contained in the American College of Cardiology/American Heart Association Guidelines for Management of Patients with Acute Myocardial Infarction and Guidelines for Percutaneous Coronary Intervention will be used to guide care provided in primary PCI programs.	**Yes**	**Yes**
	ii) Nursing and technical staff in both the catheterization laboratory and in pre and post-procedure care units will require additional training, including familiarization with angioplasty equipment, commonly used drugs, intra-aortic balloon counterpulsation equipment, patient transfer to and from the laboratory; and other pre-and post-procedure care issues.	**Yes**	**Yes**
	iii) The logistical issues that need to be addressed in the primary PCI development program include at a minimum: hours of operation, who obtains consent, mechanisms to gather staff, mechanisms to assure availability of staff and catheterization laboratory, plans for recurrent ischemia or infarction, plans to determine the responsible physician during and after primary angioplasty, plans for failed angioplasty, and fall-back plans for primary angioplasty system failure.	**Yes**	**Yes**
	iv) The quality and error management component of the primary angioplasty development program should give special emphasis to minimizing, discovering, reporting, and correcting error in the system of acute MI care.	**Yes**	**Yes**

Patient Groups Suitable for Primary Angioplasty in Settings without On-Site Cardiac Surgery	a) ST-segment elevation myocardial infarction (or new LBBB or ST-depression V1-V2 compatible with true posterior infarction) who are thrombolytic eligible or thrombolytic ineligible. b) When transfer to a tertiary institution may be harmful for patients with acute myocardial infarction in cardiogenic shock that the treating physician(s) believe, either because the patient is too unstable or because the temporal delay will result in worse outcomes. c) Patients for whom the primary PCI system was not initially available, who received thrombolytic therapy that subsequently failed. These cases should constitute no more than 10 percent of all cases.	**Yes** **Not Applicable** **Yes**	**Yes** **Yes** **Yes**
Minimum and Optimal Institutional Volume	All institutions should perform a minimum of 36 and optimally 49 primary PCI procedures annually. *(Note: A program performing at least 49 cases annually, or approximately one case per week, is more likely to have the logistics and staff available for timely reperfusion of acutely ill patients. If, however, rapid access to a program doing 49 cases is not available, then a site performing 36 or more cases/year is acceptable. This approach acknowledges important regional differences in access to primary PCI services. The lower volume standard should only be considered in areas of the state where access to a high volume program is not readily available.)*	**Yes**	**Yes**
Process and Outcome Measures for On-Going Quality Assessment	Monitoring of the outcomes of care for patients presenting with ST-elevation MI will facilitate on-going quality improvement efforts and provide the opportunity to measure program compliance, safety, and effectiveness. This requires that a uniform data set be developed, collected, and analyzed from all hospitals in Maryland offering primary PCI services. This data set should build upon the elements collected in the C-PORT project. Included would be data on: patient demographic and clinical characteristics; times of symptom onset, arrival in the emergency department, arrival in the catheterization lab, catheterization procedure onset and termination, balloon inflation, procedural outcome; complications; need for emergency cardiac surgery; incidence and indication for hospital transfers, adjunctive medical therapies and clinical outcomes (including in-hospital mortality and stroke and long-term follow-up).	**Yes**	**Yes**

Appendix D
Steering Committee Meeting Minutes

Summary of the Meeting
of the
Advisory Committee on Outcome Assessment in Cardiovascular Care

March 4, 2002
Medical School Teaching Facility
University of Maryland Medical School, 2nd Floor Atrium

Commissioners and Staff Present
James Scheuer, M.D., Chairman
William A. Baumgartner, M.D.
James L. Field, DBA
Scott Friedman, M.D.
Bartley Griffith, M.D.
Jeffrey D. Jones, M.D.
Steve B. Lowenthal, M.D.
Mark Midei, M.D.
Luis Mispireta, M.D.
Eugene R. Passamani, M.D.
Sidney C. Smith, M.D. (by telephone)

Commissioners and Staff Present
Commission Chairman
Donald E. Wilson, M.D.

Commission Staff
Barbara G. McLean
Pamela W. Barclay
Dolores Sands
Bridget Glazebrook

Consultant
Andrew G. Cohen

Committee Members Absent
Georges C. Benjamin, M.D. (Ex-Officio)

Members of the Public Present
Clarence Brewton, MedStar Health
Lucy Ferko, St. Joseph Medical Center
Sean Flanagan, St. Joseph Medical Center
Wynee Hawk, Greater Baltimore Medical Center
Gary Jones, Shore Health System
Sandra Mann, Johns Hopkins Medicine
Martha Nathanson, LifeBridge Health
Jack Neil, Anne Arundel Medical Center
Vanessa Purnell, MedStar Health

1. Welcome, Opening Remarks, and Introductions

Donald E. Wilson, M.D., convened the meeting at 6.30 p.m. with a welcome to those present and introductions of James Scheuer, M.D., Chairman of the Advisory Committee; Barbara G. McLean, Executive Director of the Commission; and Pamela W. Barclay, the Commission's Deputy Director for Health Resources. Dr. Wilson briefly discussed the goals of the Commission in establishing the Committee. He noted that Dr. Georges C. Benjamin has been appointed as a member. Dr. Wilson announced that the Commission will appoint three additional members within the next few weeks. Committee members and Commission staff then introduced themselves.

2. Overview and Background

Ms. McLean provided a brief overview of the mission and vision of the Maryland Health Care Commission, referencing the *Report to the Governor: Fiscal Year 2001*. She also presented a brief description of the activities and programs of the Commission.

3. Review and Discussion of the Advisory Committee Charge, Structure, and Timetable

Advisory Committee Charge

Ms. Barclay briefly reviewed the charge of the Advisory Committee on Outcome Assessment in Cardiovascular Care, referencing material provided to the Advisory Committee. The Commission has requested that the Committee identify quality measures to assess outcome, study models available for improvement in cardiovascular care, review policies governing how cardiac services are organized, and identify strategies for developing inter-hospital transport for specialized cardiac care services.

Timetable

Ms. Barclay outlined the timetable for the Advisory Committee to submit an initial report to the Commission by July 1, 2002. The goal is to submit a final report to the Commission by January 1, 2003.

Dr. Sidney Smith asked about the likely starting times of the meetings, and whether the meetings are open to the public. Ms. Barclay said that the meetings are most likely to be in the evenings to fit everyone's schedules, but all members will be polled to find the most suitable times and dates. Ms. Barclay confirmed that the meetings of the Advisory Committee are open to the public.

Dr. Eugene Passamani asked whether the charge was limited to hospital-based services only. Ms. Barclay noted that a subcommittee will be established to study long-term issues, such as screening and prevention.

Dr. Passamani asked about the level of funds available to achieve the objectives set out, for example, the collection and analysis of data. Dr. Scheuer pointed out that the Committee would be short-lived; however, the continuing process will cost money. The committee will discuss and develop recommendations on how to fund an on-going quality improvement process.

Subcommittees

Subcommittees will be established to address the objectives of the Committee's charge. These will include Subcommittees on Data Reporting, Interventional Cardiology, Long Term Issues, and Inter-Hospital Transport. Ms. Barclay said that additional individuals will be invited to contribute to the subcommittees.

Dr. Scheuer invited the members of the Committee to recommend individuals who can make special contributions to the subcommittees. The recommendation should include supporting information.

Dr. William Baumgartner commented that some of the subcommittees would cover one or more issues raised by the Committee's charge.

Dr. Scheuer stated that the biggest impact relates to primary care and prevention and asked about recommendations on non-acute interventions. Dr. Smith expressed the view that the Committee should look at performance measures for non-acute cardiovascular care, adding that the criteria of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) are moving in that direction. Dr. Luis Mispireta asked if the data reporting was to include all areas, angioplasty as well as surgery. Dr. Scheuer responded yes to Dr. Mispireta's question.

Mr. James Field commented that outcome data used by consumers is often different than that provided to clinicians. He further said one reporting method may not necessarily meet both needs. Dr. Scheuer responded that this is the type of issue that needs to be dealt with in the subcommittees and brought back to the Steering Committee. Dr. Scheuer added that some States have done both in regard to releasing outcome data to the public and clinicians, and those decisions need to be made considering the Freedom of Information Act.

4. Presentation: Overview of National, Regional, and State Quality Improvement Initiatives

Mr. Andrew Cohen presented a profile of national, regional and state quality improvement initiatives. He also explored a number of possible elements to be incorporated in a Maryland Cardiovascular QI Model. These included:

- Where Should CV QI be Focused? There is a continuum of care from prevention to medical treatment to procedures. Other states have focused on one or more areas, and Maryland needs to decide where it wants to focus.
- What Elements of QI? Different programs in other states include components ranging from structure to process to outcome.

Dr. Baumgartner asked for clarification of the term "Round Robin" as a "process" element. Mr. Cohen explained that it is a method used by Northern New England to identify "best practices," where the group organized "round robin" site visits among the involved hospitals. Site visit teams from each hospital, consisting of cardiac surgeons, perfusionists, nurses, and administrators, reviewed how care was delivered at other centers.

- What Should be the Terms of Participation? Options available are voluntary or mandatory involvement; there are pros and cons for each.
- Who Should Sponsor? Options available include providers, partnerships and State, with potential combinations of the three options available.

- How Should QI Data be Reported? Maryland needs to decide whether to share outcome data with peers only or with the public as well. In States where mandatory reporting is required, data is shared with the public. Studies have found that the public has not necessarily changed the way they choose services based on the reporting of public data.

A sixth question was raised: Who will pay for it?

Dr. Mispireta suggested that the Committee does not need to think of this issue as a single unit. For example, data collection may be one cost, and data management may be another cost.

Dr. Passamani commented on the phrasing of "either/or" and suggested that a sequence of effort is required. He said that the aim is to help hospitals keep going in the right direction, and to nudge them away from making mistakes. The primary focus should be on the providers, as consumers may have difficulty interpreting the data.

Dr. Steve Lowenthal said that regardless of the intended target audience, the public would gain access to the information. He suggested the development of a system that will help practitioners, but inform the public. Dr. Scheuer confirmed this view by saying that New York originally intended its report only for providers, but a lawsuit resulted and the information became available to the public. Mr. Cohen described one state that established a private, not-for-profit organization to shelter or protect the data. Dr. Lowenthal said that the report should be open to the public, as ultimately the public will be concerned.

Mr. Field raised the issue of the burden and cost of data collection, and suggested the need to set firm objectives and reasons to collect. The current group has the benefit of other states' experiences and should draw on that.

Dr. Scheuer questioned how Maryland will know whether cardiovascular care has improved if the current quality of cardiovascular care in the state is not known.

Dr. Mispireta shared his experience of collecting data for 20 years, and said that once an institution has the infrastructure, data collection is easier to do. Dr. Mispireta added that most institutions already collect and use data internally. He said that all are concerned about physician profiles, but it is the way to improve the process. Dr. Passamani reiterated that the data must be collected carefully. Dr. Mispireta stated that this is an opportunity to collect unbiased data. Dr. Baumgartner felt that the process could be used as an academic exercise. Northern New England has done this extremely well; with two of the best medical schools in the country, Maryland could do likewise. Dr. Scheuer suggested a cost-benefit analysis could result from the process.

5. Future Meeting Schedule

Dr. Scheuer announced that the next meeting would be on Wednesday, April 17, 2002. Dr. Scheuer said that Kenneth I. Shine, M.D., has been invited to speak. Dr. Shine is President

of the Institute of Medicine, National Academy of Sciences, and he chairs the New York State Cardiac Advisory Committee.

Dr. Scheuer discussed the necessity and process of the subcommittees and their charges. He asked each Committee member to serve on at least one subcommittee, and invited the members to nominate other appropriate candidates. Dr. Scheuer emphasized that it is hoped that by mid-June progress would have been made towards certain goals for the mid-year report.

Ms. Barclay asked the Committee members about the most efficient mechanism to communicate. The general consensus was by email. Another meeting will be planned for June after a poll is taken to identify a date and time.

Ms. McLean requested that the members provide the requested information within 2 weeks of the current meeting. Ms. Barclay said that the Commission wishes to involve as many people as possible in the subcommittee process and will also draw from a pool of persons who were interested in serving on the Steering Committee.

Dr. Scheuer asked if the Committee members would like to invite other speakers with experience in a particular subject matter. Dr. Bartley Griffith recommended Dr. Bill Nugent, Chief of Cardiothoracic Surgery at Dartmouth-Hitchcock Medical Center, who is an inspirational speaker and has experience in the process and the debate about voluntary versus mandatory reporting. Dr. Nugent works with the Northern New England Cardiovascular Disease Study Group, a regional collaborative model. Dr. Passamani seconded that recommendation. Dr. Baumgartner recommended Laurie Shroyer, Ph.D., who has worked within the federal Veterans Affairs (VA) system and is able to present statistical methods in a straightforward manner. Dr. Shroyer created the statistical modeling for risk adjustment with Karl Hammermeister, M.D. Dr. Scheuer reminded the group that the Committee members also have vast experiences, such as Dr. Smith, who could speak on the Guidelines for Percutaneous Transluminal Coronary Angioplasty.

6. Other Business

There was no other business.

7. Adjournment

The meeting adjourned at 7.40 p.m.

Summary of the Meeting
of the
Advisory Committee on Outcome Assessment in Cardiovascular Care

April 17, 2002
Medical School Teaching Facility
University of Maryland Medical School, 2nd Floor Atrium

Committee Members Present
James Scheuer, M.D., Chairman
William A. Baumgartner, M.D.
Georges C. Benjamin, M.D. (Ex-Officio)
James L. Field, DBA
Scott Friedman, M.D.
Bartley Griffith, M.D.
Jeffrey D. Jones, M.D.
Vahe Kazandjian, Ph.D.
Steve B. Lowenthal, M.D.
Thom A. Mayer, M.D.
Mark Midei, M.D.
Luis Mispireta, M.D.
Hilary T. O'Herlihy, M.D.
Eugene R. Passamani, M.D.
Sidney C. Smith, M.D. (by telephone)

Commissioners and Staff Present
Commission Chairman
Donald E. Wilson, M.D.

Commission Staff
Barbara G. McLean
Pamela W. Barclay
Dolores Sands
Bridget Glazebrook
Patricia Cameron
Susan Panek
Debbie Rajca
Colleen Lates

Members of the Public Present
Vanessa Aburn, Union Memorial Hospital
Angelyn B. Estwick, Master of Public Health Candidate, George Washington University
Lucy Ferko, St. Joseph Medical Center
Sean Flanagan, St. Joseph Medical Center
Wynee Hawk, Greater Baltimore Medical Center
Gary Jones, Shore Health System
John J. Kennedy, M.D., Anne Arundel Medical Center
Sandra Mann, Johns Hopkins Medicine
Jack Neil, Anne Arundel Medical Center
James K. Porterfield, M.D., Greater Baltimore Medical Center

1. Call to Order and Introductions

Dr. Scheuer called the meeting to order at 6.30 p.m. Members of the Advisory Committee, the Chair of the Commission, and Commission staff introduced themselves. It was announced that three new members joined the Committee. Vahe Kazandjian, Ph.D. is the President of the Center for Performance Sciences, MHA: The Association of Maryland Hospitals and Health Systems; Thom A. Mayer, M.D. is the Chair, Department of Emergency Medicine,

Inova Fairfax Hospital; and Hilary T. O'Herlihy, M.D. is the President of the MedChi Board of Trustees.

2. Approval of the Minutes of the Previous Meeting (March 4, 2002)

On motion of Eugene R. Passamani, M.D., which was seconded by Scott Friedman, M.D., the minutes of March 4th were approved.

3. Presentation: Challenges in Developing a Maryland Cardiovascular QI Model

James Scheuer, M.D. introduced Kenneth I. Shine, M.D., President of the Institute of Medicine (IOM), National Academy of Sciences, and Professor of Medicine Emeritus at the University of California, Los Angeles (UCLA) School of Medicine, and Chairman of the New York State Cardiac Advisory Committee. Dr. Shine is UCLA School of Medicine's immediate past Dean and Provost for Medical Sciences. Currently, he is Clinical Professor of Medicine at the Georgetown University School of Medicine.

A distinguished cardiologist, Dr. Shine received his M.D. from Harvard Medical School and completed most of his advanced training at Massachusetts General Hospital (MGH), where he became Chief Resident in Medicine. Following his postgraduate training at MGH, he held an appointment as Assistant Professor of Medicine at Harvard Medical School. He moved in 1971 to the UCLA School of Medicine and became Director of the Coronary Care Unit, Chief of the Cardiology Division, and subsequently, Chair of the Department of Medicine. His many leadership roles have included President of the American Heart Association.

Dr. Shine prefaced his presentation on the experience in New York regarding the issues, pros and cons related to implementing a Cardiovascular QI Model by referring to a letter addressed by Dr. Shine to a California State Senator (dated April 20, 2001), which he distributed to Committee members. In 2001, the California legislature passed Senate Bill 680, a mandatory reporting law, and California's Office of Statewide Planning and Development (OSHPD) is now instituting a similar program, the Coronary Artery Bypass Graft Mortality Reporting Program. Prior to SB680, participation in the program was voluntary. Dr. Shine noted that QI programs are unique to each State; however, there are lessons that can be shared.

California collects data on pre-operative risk factors (e.g., ejection fraction, urgency of the procedure, age, and sex of the patient) and in-hospital surgical mortality associated with the CABG. As noted, hospitals are voluntarily providing the data for the program, at this time.

The New York State Cardiac Advisory Committee has a history of more than 25 years and started as a CON committee. Dr. Shine was appointed Chair in 1994. The New York Advisory Committee is traditionally chaired by someone from outside the State of New York, with another four to five members also from outside. Utilizing expertise from outside minimizes any internal conflicts of interest as new programs and policies are established. Out-of-state members are also helpful as site visitors.

In 1989, New York began to look at measuring outcomes. A key element of success was an alliance with Edward L. Hannan, PhD., Professor at the University at Albany who assisted with the statistical analysis and risk adjustment, forming the template for the reports. It is essential to perform risk adjustment for meaningful results. In New York, risk factors are applied to the performance of individual institutions and physicians. The risk factors are based on actual experience versus a theoretical construct, and vary from year to year.

The approach used since has been to collect data, especially on mortality, for all patients; identify risk factors each year and then apply them to individual institutions and surgeons throughout the state. The database now contains a large amount data (about 20,000 patients with coronary bypass procedures and 40,000 with PTCA procedures), which is regularly mined for research. Investigators have access to the data. Initially the information was intended to be confidential; however, following a Newsday Freedom of Information (FOI) lawsuit, the institutional information was made public, but not the individual data. Dr. Shine felt that institutional performance improved as a result of publication.

In 1989, the first year of reporting, the top tercile (one-third) of hospitals had a risk-adjusted mortality rate of 2.46% for CABG surgery, whereas the lowest tercile had a rate of 8.97%, a three-fold difference in outcome between the best performing and worst performing hospitals. By 1992, the quality gap had shrunk, with the highest tercile averaging a risk-adjusted mortality rate of 2.20%, while the lowest tercile had a risk-adjusted mortality rate of 2.8%. This trend continues with the State average at about 2.2%, the top tercile at 1.8%, and the lowest tercile at 2.7%.

It has been found in New York's experience that there have been no changes in the way physicians refer or the way managed care organizations (MCO) purchase services as a result of publication of information on hospitals. MCOs still purchased the cheapest care. Referrals out of state did not increase. However, there has been a significant change in the governance of the hospitals. One such result has been the reduction in the number of "low-volume" surgeons operating. These "low volume" surgeons often had the highest mortality rates.

Regular audits of the data take place. Some are conducted on a random basis; some are conducted when disagreements occur between the hospital and report data, or as flags are raised (for example, an increase in a diagnosis of ventricular aneurysms that may be evidence of "gaming"). Those cases require audit before publication of the data. Generally, when an outlier hospital (more than two standard deviations above the mean) occurs, it is a system-of-care issue (a problem in the institution, not a random variation). For example, one hospital with high risk-adjusted mortality rates was found to have good outcomes for elective patients, but poor outcomes for unstable patients admitted through the emergency room. An investigation found that the patients were not being stabilized before surgery, unlike elsewhere. Consequently, the system was changed so that unstable patients were stabilized in the emergency room prior to transfer to surgery. The outcomes improved dramatically. The surgeons were very capable technically in the operating room, but the process for getting the patients to the operating room was unsatisfactory.

Dr. Shine provided a number of other examples, demonstrating how quality data can be used to identify problem areas and improve outcomes. Citing a case in Rochester, he reiterated that the State must be alert to the issue of "gaming." He also noted the challenge of collecting 30-day mortality data.

Initially, the program in New York started with data reporting only on CABG; however, it has now been extended to coronary angioplasty, pediatric cardiac surgery, and valve surgery. New York is now exploring an evaluation of the outcomes of care for acute myocardial infarction. Thomas J. Ryan, M.D. is leading this effort. For myocardial infarction there are many more hospitals involved, with new issues to be covered. New York State provides software to the hospitals being evaluated so that they can perform their own analysis. The State encourages ongoing analysis; however, only about one-third do so. Most institutions wait to be notified with the data and then respond to the final assessment.

Results have shown that even at internationally renowned institutions, some individual surgeons have mortality rates three or four times higher than their colleagues. The New York Advisory Committee has no authority or responsibility beyond reporting the results to the institution when the institution itself, on the whole, is doing well. This lack of authority can be frustrating.

Currently, the NY State Advisory Committee is examining freestanding angioplasty (that is, hospitals performing angioplasty without cardiac surgery). The Committee looked first at the C-PORT protocols, which were found to be somewhat problematic during the trial; however, the registry is well set up. A task force has established protocols for such facilities under strict conditions, requiring quarterly reporting, including volumes and demographics.

The Committee derives its influence from being advisor to the State Department of Health. Although politics may enter into the outcome of a CON, the State has never approved a program that was medically unsafe.

As an example of how quality improvement may be addressed, Dr. Shine cited a recent focus on examining the equity of cardiac surgery for minorities in New York City. Currently, there are 14 programs offering catheterizations, and 10 performing cardiac surgery. It has been found that if catheterizations are performed at a full service hospital (that is, a hospital with cardiac surgery), minorities receive cardiac surgery at the same rate as the white population, if corrected for insurance coverage. However, if catheterizations are performed at a hospital without surgery, 82% (± 2%) of Whites receive surgery, high 60% for African-Americans, and 40% for Hispanics.

Dr. Shine described an experimental program involving Medicaid payment for procedures that meet the RAND criteria for necessity. Medicaid pays the hospitals well, but not the surgeons. The issue is whether the catheterization hospital or the surgery hospital will make the application to Medicaid.

Another example of how quality improvement may be addressed was cited. A hospital in Brooklyn currently has poor surgical outcomes, and it is evident that it has a low-volume

program and that the institution is not making a large investment in the program. Those who are aware of the program's predicament often opt out and go to another facility to receive care. In New York, strict criteria are in place when a new program is established. However, in order to improve quality, New York will issue a CON to another institution in this region, if it meets the criteria, despite the rules that prohibit a new program when an existing one is at low volume. The new program must meet strict guidelines for screening, evaluation, and other requirements for cardiac surgery. Clear objectives and goals for the program must be set out and followed. The CON is initially granted for five years only. It is hoped that introducing a new program will provide competition and an incentive to the poor performing hospital to improve.

Initially, many of the surgeons in New York were suspicious of the data reporting. It was argued that surgeons might not operate on the sickest patients for fear of increasing their mortality rates. It was also argued that more patients might be sent out of state for surgery if they were high risk. Analysis of the data contradicts both arguments.

Dr. Scheuer thanked Dr. Shine for his presentation and said some of the salient points to be learned were how data collection can be used for corrective action; how material can be used for research, and for new programs to address inequities in health care. Dr. Scheuer opened the floor for questions.

Luis Mispireta, M.D. asked for clarification of issues concerning the logistics of data collection and the definition of freestanding catheterization labs. Dr. Shine responded that freestanding catheterization labs referred to facilities performing primary angioplasty only, and not elective procedures; for example, the facilities involved in C-PORT were a source of data collection and analysis. In regard to data collection, Dr. Shine felt that a nurse coordinator was most frequently responsible for such duties. The Advisory Committee provides the software to assist in data collection and reporting; however, the institution was responsible for the actual collection and must bear the cost. Considering this, it is important to critically select data variables. For example, originally EKGs before and after were required. However, it was found to have no significant impact on outcome and was consequently removed to reduce unnecessary burden.

Dr. Mispireta thanked Dr. Shine for his comments, and also noted that cooperation is essential in such activities and that the data can be used as benchmarks with other states.

Dr. Shine responded that New York is trying to make the methodology as transparent as possible, and a sub-panel has been created to increase the exchange and identity of data. The Society of Thoracic Surgeons (STS) has done an outstanding job, but New York has the benefit of having data from all institutions. Dr. Shine has confidence in the majority of the data reported from the institutions. However, this highlights the importance of carefully selecting data variables. The pilot for Myocardial infarction (MI) which involves many more hospitals and possible risk factors, is being carried out initially with hospitals that are already involved with data collection, before expanding to rural hospitals, to streamline the process and to identify any potential problems.

Sidney C. Smith, M.D. commented that New York is a model program for exactly what the ACC/AHA committee aimed to do. He wanted to know how the State audits and adjudicates hospitals' results.

Dr. Shine informed those present that Dr. Smith has been a consultant for the New York Advisory Committee and New York has tried to use the ACC/AHA guidelines as much as possible. When data comes in from the hospitals, the Health Department staff reviews the data for completeness and flags any potential errors. If the results of the data are different between the hospital and health department, a meeting is organized to resolve the issues, and reasons are discussed for possible causes of increased or decreased mortality, or dramatic change in number of procedures. Following these meetings, there are rarely any difficulties in resolving data and interpretation issues. After an analysis and conclusion, the report is sent to individual hospitals to respond to results. After the initial release to the hospital, the hospital can challenge the analysis or conclusions. Nothing is released until the individual hospital has a chance to respond. Initially, this process was time-consuming; however, it is streamlined now.

Eugene R. Passamani, M.D. asked whether any false paths were taken (so that Maryland can avoid them); importance of the statistical center and how to set it up; and whether there are instances of special cause variation, where the cause of variation cannot be identified.

Dr. Shine responded that institutional reporting should not be secret. The Institute of Medicine has recommended that institutional reporting at the State level is valuable. Dr. Shine also said that asking for too much data should be avoided.

Dr. Shine reported that the data analysis is completed by an independent consultant outside of the health department. Neither the Department of Health nor the Committee can manipulate the independent statistician.

It is not always possible to identify reasons for variations. If there is a variation in one year only, there may be no real concern; however, when there is a variation sustained or outlier present over a number of years, there is more pressure to solve it. At this stage, site teams (typically consisting of cardiologist, surgeon and nurse) are sent to the institution, where it is often the nurse who will identify the problem. Unresolved variations will influence CON decisions, e.g., if a hospital requests an additional catheterization lab, the application will not be approved until the variation has been resolved. With this condition, variations are often more quickly resolved.

Hilary T. O'Herlihy, M.D. reported that as soon as the IOM report on racial and ethnic disparities in health care was released, MedChi, the Maryland State Medical Society, met with the Monumental City Medical Society, which represents African-American physicians. He said that disparity exists no matter the qualifications of the practitioner. Dr. O'Herlihy commented on the data reported by Dr. Shine regarding disparity in care for minorities, and questioned the provision for a CON in Brooklyn. It was clarified that Dr. O'Herlihy was referring to the recent IOM report, Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care (March 20, 2002), whereas Dr. Shine was commenting on a New York City study. Dr. Shine also clarified that the 5-year trial period is for new programs only and is provided with specific

performance targets. The health department will not close the existing low quality institution, but it is hoped that with competition, there will be an incentive to improve performance.

Bartley Griffith, M.D. expressed concern about the confidence of risk adjustment, and shared his experience in Pennsylvania. Dr. Griffith said that patients may not always be appropriately risk-adjusted. He also said that single surgeon outliers are rare in today's world. Generally, government is not needed in such cases; the practice gets rid of them. Dr. Shine agreed that it is impossible to say that the data is perfect; however, he felt that the data is adequately risk adjusted. Dr. Shine added that data is a moving target, requiring modifications. Dr. Griffith expressed his concern that data made public to consumers may cause more harm than good. Dr. Shine commented that, overall, most institutions with risk adjustment have good outcomes. He reiterated that persistent outliers are not differences in risk adjustment, and that there is no evidence that physicians are avoiding difficult patients.

Dr. Griffith asked Dr. Shine to comment on the way the Northern New England Cardiovascular Disease Study Group handles data. Dr. Shine responded by saying that the New England program is very useful and has made a valuable contribution. It focuses on outcomes, identifying problems, and re-education and re-training issues. Dr. Shine said that the New England group handles its data differently. He stressed the need to look at and understand the system-of-care.

4. Update on Steering Committee and Subcommittee Membership

Pamela Barclay said that there had been an overwhelming response to membership on the subcommittees. The Commission contacted those who expressed an interest in the Steering Committee, as well as Steering Committee members. In the next couple of weeks, membership will be finalized, including Chairs for each subcommittee.

5. Review and Discussion of Subcommittee Charges and Work Plans

Dr. Scheuer referenced the charges and work plans, which were included in the meeting package. Dr. Scheuer requested any comments on each of the four charges.

Dr. Mispireta commented on the charge for the Subcommittee on Quality Measurement and Data Reporting, asking about the feasibility of data collection on prevention issues, especially in the hospital setting. He wondered whether it would be better addressed under Long Term Issues. Dr. Scheuer acknowledged Dr. Mispireta's concern and felt those issues should be discussed and resolved in the subcommittees.

William A. Baumgartner, M.D. asked for clarification of the data used in the Subcommittee on Inter-Hospital Transport. Ms. Barclay and Dr. Passamani clarified that the data is Baltimore data from 1999. Mark Midei, M.D. raised the issue about triage and EMS. He said that EMS data from the field influences this topic greatly; adoption of a trauma system model for cardiovascular care in the field is potentially volatile. It is, however, related. Dr. Scheuer felt that the issue could be blended with the issues of the Interventional Cardiology group.

Dr. Passamani commented on the Subcommittee on Long Term Issues, by saying that congestive heart failure, a serious and fairly common illness, should be mentioned more prominently.

There were no comments raised on the Subcommittee on Interventional Cardiology.

6. Future Meeting Schedule

Ms. Barclay announced that the next meeting will be on June 12, 2002 at 6.30 p.m. The location is to be determined. It is hoped that the subcommittees will meet once before the June 12 meeting. Ms. Barclay said that a couple of members have not indicated a preference for the subcommittee with which they wish to work.

Dr. Scheuer asked the members to let him or Ms. Barclay know whether they would like another speaker for the next meeting and whether they would like to recommend one. Commission staff will follow up regarding subcommittee preferences.

7. Other Business

There was no other business.

8. Adjournment

The meeting adjourned at 7.45 p.m.

Summary of the Meeting
of the
Advisory Committee on Outcome Assessment in Cardiovascular Care

June 12, 2002
Metro Executive Building
4201 Patterson Avenue, Conference Room 100
Baltimore, Maryland

Committee Members Present
James Scheuer, M.D., Chairman
Robert Bass, M.D.
William A. Baumgartner, M.D.
Luther Clark, M.D.
Donald Dembo, M.D.
James L. Field, DBA
Scott Friedman, M.D.
Jeffrey D. Jones, M.D.
Steve B. Lowenthal, M.D.
Thom A. Mayer, M.D.

Commission Staff Present
Barbara G. McLean
Pamela W. Barclay
Dolores Sands
Bridget Glazebrook
Susan Panek
Debbie Rajca
Colleen Lates

Members of the Public Present
Andy Cohen, Consultant
Lucy Ferko, St. Joseph Medical Center
Sean Flanagan, St. Joseph Medical Center
Gary Jones, Shore Health System
Cheryl Lunnen, Union Memorial
Vanessa Purnell, MedStar Health

1. Call to Order and Introductions

Dr. Scheuer called the meeting to order at 6:30 p.m. Members of the Advisory Committee and Commission staff introduced themselves.

2. Approval of the Minutes of the Previous Meeting (April 17, 2002)

On motion of Steve Lowenthal, M.D., which was seconded by Scott Friedman, M.D., the minutes of April 17th were approved.

3. Presentation: Future Trends in Cardiovascular Services

James Scheuer, M.D. introduced James L. Field, Director, Cardiovascular Roundtable, Advisory Board Company. The Advisory Board is a membership of 2,000 of the country's largest and most progressive health systems and medical centers. The Advisory Board is a "think tank" in health care, publishing 50 major studies and more than 3,000 customized research

briefs each year on progressive management and clinical practices in health care, including cardiovascular research.

The Cardiovascular Roundtable, which tracks clinical and business trends and issues, focuses its research efforts on the economic and market developments in cardiovascular services. Hospitals comprise about 99 percent of the Board's business, and about 65 percent of the cardiac surgery and interventional cardiology centers in the United States are members of the Roundtable.

Dr. Field stated that it is not business as usual for Cardiovascular Programs. More events have coalesced to affect the programs. Technologies are coming and going. Cardiac services continue to grow, and are something all hospitals aspire to have. To date, cardiac surgery has been highly profitable. Profits from Medicare payments helped cardiac surgery programs generate a pool of money to cross-subsidize many other services in hospitals. After a period of being marginally profitable, catheterization laboratories have had higher profits, with stents, IIb/IIIa inhibitors, and Medicare coverage of stents. However, these margins are being offset by increasing technology costs.

Dr. Field said that the industry is in turmoil for a number of reasons:

1. Drug-eluting stents

This new technology has the prospect of leading to an increasing transition of cardiology cases from the operating room (OR) to the cath lab, with less morbidity and time spent in the hospital. Restenosis now develops in about 20 – 30 percent of cases, requiring at least one or more additional interventions in one year. Drug-eluting stents have the potential to address the restenosis problem by giving off, or "eluting," drugs to the site of the blockage, aimed at preventing the restenosis from occurring and possibly eliminating the need for additional procedures at the blockage site. There have been early spectacular results. In a USA trial (n= 1,100) revascularization was decreased with patient outcomes at 4 and 8 months showing only 4 percent with restenosis. These results are not as perfect as those of the European study, where none of 120 patients who were implanted with the drug-eluting stent experienced coronary restenosis in the six months following stent placement. At this stage, it cannot be determined if drug-eluting stents prevent or defer restenosis. Cordis, a division of Johnson & Johnson, is expected to introduce this technology in the first quarter of next year (2003). The best case scenario for approval is about six months; the worst case, still less than one year. The federal Food and Drug Administration (FDA) is expected to fast-track the review and approval of the application after a July submission of the trial results to FDA.

The cost of this new technology will be significantly more than the bare-metal stent. The current stent has a cost of $800 - $1,100, while the new drug-eluting stent is expected to cost $3,200 per stent. Cordis will initially have a monopoly on the product for some time to come, with no pricing competition. This added cost will take cath labs into the red on these cases. The low margins that currently exist in labs will dissipate and hurt hospitals. The conversion rate to use will be quick, causing a step function increase in cath lab costs.

A trailing effect will result from the potential of drug-eluting stents to eliminate a significant number of cardiac cath lab procedures for in-stent restenosis. A major financial impact on the cardiac service line is expected if cardiac surgery volumes (coronary artery bypass grafts) also decrease 50% in the next five years as some expect.

Task groups have been set up to investigate the impact on cardiac surgery and hospital income. The current thought is to put on hold developing any extra capacity. Integrated systems in particular are not hiring cardiac surgeons or adding cardiac ORs. It is projected that a number of current CABG cases will instead go to the cath labs and interventional cardiologists will be able to treat them (e.g. patients with diabetes) more aggressively. This is a sobering development for cardiac surgery. It is expected that there will be a huge influx in cath lab cases and then the volumes will stabilize. It is thought that there will not be more single/double vessels or uncomplicated cases, but rather complicated cases, which are now treated in the OR. However, no one has examined in a disciplined fashion the type of disease that will be treated in the cath lab instead of the operating room; this issue requires closer examination.

2. Primary angioplasty – for hospitals with no OHS back-up

The ability of a hospital to perform primary angioplasty without open heart surgery (OHS) back-up is dependent on each State's regulations and varies by state. However, providers are increasingly demanding such capabilities, particularly due to the results and outcomes of the C-PORT trial. For some States, there is no barrier to performing such procedures. Soon providers will also be requesting the ability to perform elective cases without surgical back-up, and movement toward performing elective cases will have a domino effect. For example, TriStar Health System in Nashville has five or six hospitals doing primary angioplasty without on-site OHS. There is a low incidence of emergent surgery. The old rules about who should provide interventional cardiology are going by the wayside. Cath labs are becoming the emphasis rather than cardiac ORs. Hospitals with cath labs but no surgery may partner for back-up with a hospital that performs OHS.

3. Volumes overall

With an aging population, the total number of cardiac procedures is increasing. The general sense is that there is a flat or declining curve for OHS volume, especially CABG, while interventions in the cath lab are increasing. This pattern of increase is expected to accelerate earlier and more dramatically with the introduction of drug-eluting stents.

4. Pacing

Pacing or cardiac resynchronization therapy is the latest technology in treating heart failure, and has been successful in trials so far. It may be appropriate for that 20-30% of CHF cases with conduction defects, and it may be combined with implantable cardioverter defibrillators (ICD), with the potential for many patients to receive it. Hospitals will probably lose money on each device they implant. Manufacturers have strategically priced the devices so that the hospitals will lose about $3,000 - $5,000 per procedure (the device costs about $16,000, and implanting it costs the hospital about $18,000 to $20,000, including the device, leads and care). This will come on the heels of the other financial impacts.

5. Number of new OHS programs

Within the last year, announcements or recent openings of 54 programs were identified by the Advisory Board. This number is based on the number of programs identified, through literature searches, business reviews and internet sources, to be in the final stages of planning, currently breaking ground or have been open for less than a year. There are approximately 2 to 3 new OHS/Interventional programs opening or planning to open each week around the country. This rate of increase in programs is shocking with the impact of drug-eluting stents not being factored into the analysis of need. The new programs are driven by market competition rather than the need to serve a population that does not now have access to care and needs to travel miles and miles to receive it. The established programs are under attack. Often the new programs are extensions of major centers, intended to refer ("feed") the more complex cases to the large tertiary centers. This process is having an impact on administrators by siphoning off the business of existing programs and reducing volume expectations to around 200 cases per year (in the case of one program, 150 per year). Average program volumes are currently around 200 to 225 cases; if this continues to drop any further, volumes will drop below the quality threshold of 200. Weeding out low-volume programs is not likely to happen, raising both political and quality issues.

6. Shortage of cardiologists

Two or 3 years ago, there was considered to be a general oversupply of cardiologists. However, today there is a shortage, especially in "outlying" areas. Access is better in wealthy suburbs. A successful program relies on the right number of cardiologists to refer patients into the program. A lack of cardiologists will impede the growth of a program.

When all of the above issues are considered, the outlook for cardiac programs is not as rosy as 2 to 3 years ago. From the patients' and cardiologists' points of view, better technology and skills of surgeons have increased quality and access. However, for hospital administrators, the financial impact could be severe.

Dr. Scheuer began the questions by asking Dr. Field to elaborate on ICD and changing indications. Dr. Field responded by saying that ICD is used in the prevention of sudden deaths. The new technology poses the question of implanting two devices or one super device. Manufacturers are pushing the high-end devices, with higher costs, and hospitals are not being paid adequately for such devices. The ability to pay for this technology is an issue for Medicare and private payers.

Ventricular assist devices and their technology do extend the survival of patients waiting for transplantation. They are considered meaningful; however, the current generation's problems include machine failure and sepsis. There is no money earmarked for the new generation of such technologies, which would generate billions of dollars of expenses. Medicare does not have the funds to pay for them.

Luther Clark, M.D. asked whether the devices were net losses for the hospitals. Dr. Field said that the losses flow through to other service lines, although no studies have been completed to demonstrate this. Hospitals are unable to recover direct costs of care and therefore there is a direct hit to the bottom line. In general, profitability is decreasing – reimbursements have gone

down and costs have gone up. There is always a lag between new technology and Medicare reimbursements. For drug-eluting stents, the Medicare lag is expected to be approximately 2 years. Hospitals must cover the costs until then.

Donald Dembo, M.D. asked Dr. Field to comment on the primary and secondary prevention of heart disease and the long-term impact of the preservation of individuals with cardiovascular diseases. Dr. Field stated that he was not an expert in prevention. Referring to the March meeting of the American College of Cardiology, Dr. Dembo noted that the potential of statin drugs to reduce the incidence of cardiac events, an important consideration as the Medicare population grows. Dr. Scheuer stated that prevention is being addressed by the Long Term Issues Subcommittee, and that it is likely that primary and secondary prevention may have a more profound effect than some of these technologies on cardiovascular disease.

Dr. Scheuer thanked Dr. Field for his presentation, which he described as sobering and discouraging, but important.

4. Subcommittee Reports and Discussion

On behalf of the chairmen, Pamela Barclay presented the reports for Long Term Issues (Eugene Passamani, M.D.) and Quality Measurement and Data Reporting (Luis Mispireta, M.D.) subcommittees, both of which have met once. The Interventional Cardiology and Inter-Hospital Transport subcommittees have not met to date.

Each subcommittee has been set up so that there will be a liaison between the subcommittee and Steering Committee. The chairman of each of the subcommittees, who is a member of the Steering Committee, will bring back issues to the Committee and discuss recommendations.

Quality Measurement and Data Reporting

The subcommittee members discussed the charge that had been presented to them. There was a consensus that the starting point would be to survey existing OHS programs to see what data they were currently collecting (e.g., data submitted to the national Society of Thoracic Surgeons (STS) database) and how it was being used. Staff is drafting a survey, which will be reviewed by the subcommittee before being sent to the applicable hospitals.

Long Term Issues

The subcommittee received three background presentations as an introduction to the issues.

- Healthy People 2010 Project - Jeanette Jenkins, Director, Office of Health Policy, Community Health Administration, DHMH
- Congestive Heart Failure - Edward Kasper, M.D., Associate Professor of Medicine and Director of the Cardiomyopathy and Heart Transplant Service, Johns Hopkins School of Medicine

- Congestive Heart Failure: Patient Outcomes Clinical Trials - Thomas Aversano, M.D., Cardiologist, Johns Hopkins School of Medicine

Members were polled on other areas they would find beneficial to focus on.

The subcommittees also identified potential speakers, including William C. Nugent, M.D., of the Northern New England Cardiovascular Disease Study Group. It is hoped that he will be available to present to the Steering Committee and the Quality Measurement and Data Reporting Subcommittee members. William A. Baumgartner, M.D. offered to assist by following up an email message to Dr. Nugent.

It was suggested that subcommittee updates should be added to the agenda for the subcommittees so that all subcommittees are aware of each other's activities, as there will be an overlap in some issues. Dr. Scheuer further suggested that the minutes of the meetings should be shared. Ms. Barclay agreed.

Dr. Scheuer suggested that the Quality Measurement and Data Reporting Subcommittee should look at the background information on all of the systems used across the country, including looking at the results and not just the mechanisms. Discussions are also needed on the effect of the programs on hospitals and doctors.

Dr. Scheuer suggested that the Get With the Guidelines (GWTG) project of the American Heart Association and Guidelines Applied in Practice (GAP) of the American College of Cardiology be reviewed and looked at in terms of how they can be used (i.e., whether the project should be recommended for use by all Maryland programs). Andy Cohen noted that discussion by the Long Term Issues Subcommittee is expanding beyond acute myocardial infarction (AMI) to congestive heart failure (CHF).

5. Future Meeting Schedule

Ms. Barclay stated that she would get the meetings of the Committee on the calendar for summer and fall.

Dr. Scheuer said that an interim report is due on July 1st and expressed some concern that the process has not moved as quickly as he had expected, especially in regard to the subcommittees, although he does appreciate the difficulty with time commitments. He asked the members for suggestions.

Dr. Clark suggested that meetings could be organized as teleconferences with some people meeting in person. Dr. Baumgartner suggested that planning several meetings in advance, rather than one at a time, might be beneficial. It is important to get the meetings on people's schedules. Dr. Scheuer suggested scheduling two subcommittees in an afternoon for about 2 hours, each with a good agenda, followed by two the following morning, and a Steering Committee soon after. Ms. Barclay said that the meeting of the Long Term Issues Subcommittee lasted two hours, with the meeting of the Quality Measures and Data Reporting Subcommittee being shorter. She has found that the evenings have generally been a better time to meet for the

people involved. Dr. Scheuer felt that members could invest 2-3 hours one afternoon (e.g., 2:00-5:00 p.m., or 3:00-6:00 p.m.), and then revert to evenings. Dr. Baumgartner felt that most people are willing to put the time in, but such meetings would need to be planned ahead.

Robert Bass, M.D. suggested polling people and developing a regular pattern for the meetings (e.g., first Monday of the month). Dr. Baumgartner felt that teleconferences could be productive, if people come prepared and have done the appropriate reading of materials supplied. Thom A. Mayer, M.D. also suggested supplementing meetings with emails to keep members up-to-date. Dr. Mayer added that conference calls work well especially after a face-to-face initial meeting.

Dr. Field inquired what the end-results of the subcommittees were, and suggested that there needs to be a strong sense of what needs to be done and to keep the work focused. Dr. Scheuer wondered whether forming an executive subcommittee would be valuable to work with the Chairmen and assist in the focus and progress. Ms. Barclay felt that the subcommittees have a sense of their purpose and all have been provided with the charges. She offered to review and refine the charges as needed. Barbara McLean stated that the two subcommittees that have met have made progress.

6. Other Business

There was no other business.

7. Adjournment

The meeting adjourned at 7:40 p.m.

Advisory Committee on Outcome Assessment in Cardiovascular Care

Summary of the
Joint Meeting of the Steering Committee and
Quality Measurement and Data Reporting Subcommittee

Wednesday, October 2, 2002
BWI Airport Marriott Hotel
1743 West Nursery Road
Baltimore, Maryland 21240

Steering Committee Members Present
James Scheuer, M.D., Chairman
Luis Mispireta, M.D.*†, Subcommittee Chairman
Robert Bass, M.D.
William A. Baumgartner, M.D.*†
Luther Clark, M.D.
Donald Dembo, M.D.
Scott Friedman, M.D.
Steve B. Lowenthal, M.D.
Thom A. Mayer, M.D.
Hilary T. O'Herlihy, M.D.
Eugene Passamani, M.D.

Subcommittee Members Present
Diane Alejo
James Brown, M.D.†
Mercedes Dullum, M.D.†
Susan Glover
Peter Horneffer, M.D.†
Teresa Kessell, RN
Sanjiv Lakhanpal, M.D.†
John New
Karen Sweeney, RN
Douglas Wilson, Ph.D.
Daniel Woronow, M.D. †

Cardiac Surgery Data Work Group Members Present
John Laschinger, M.D.
Anjum Qazi, M.D.

Commission Staff Present
Barbara G. McLean
Pamela W. Barclay
Patricia Cameron
Bridget Glazebrook
Colleen Lates
Susan Panek
Dolores Sands

Guest Speaker
William C. Nugent, M.D., Chief, Cardiothoracic Surgery at Dartmouth-Hitchcock Medical Center

Members of the Public Present
Sean Flanagan, St. Joseph Medical Center
Vanessa Purnell, MedStar Health

1. Call to Order and Introductions

James Scheuer, M.D. called the meeting to order at 5:30 p.m. Members of the Advisory Committee and the Quality Measurement and Data Reporting Subcommittee introduced themselves.

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*Member of the Quality Measurement and Data Reporting Subcommittee
†Member of the Cardiac Surgery Data Work Group

2. Approval of the Minutes of the Previous Steering Committee Meeting (June 12, 2002)

On the motion of William Baumgartner, M.D., which was seconded by Robert Bass, M.D., the minutes of the June 12th Steering Committee meeting were approved.

3. Review of Draft Interim Report to the Maryland Health Care Commission

Pamela Barclay presented the draft Interim Report of the Advisory Committee, and welcomed any comments or suggestions. The draft document will be submitted to the Commission at its October meeting.

Luther Clark, M.D. asked if the Interim Report included the formation of the subcommittees and the charges put to them. Ms. Barclay explained that the Interim Report is a progress report of the achievements to date of the Steering Committee and its subcommittees. The copy of the draft report provided to the committee members did not have the minutes attached, but the final version will include the minutes. Some of the subcommittees are still in the early development stage. The Advisory Committee on Outcome Assessment in Cardiovascular Care will submit a second report, which will be its final report and contain its recommendations to the Commission.

Dr. Scheuer asked the members to submit their comments on the draft document to Ms. Barclay by October 4th.

4. Presentation: Northern New England Cardiovascular Disease Study Group: William C. Nugent, M.D., Dartmouth-Hitchcock Medical Center

The purpose of the special, joint meeting was to hear a presentation by William C. Nugent, M.D., of the Dartmouth-Hitchcock Medical Center in Lebanon, New Hampshire. Dr. Scheuer introduced Dr. Nugent, who is a founding member of the Northern New England Cardiovascular Disease Study Group (NNECDSG) and is still active in the NNECDSG. The NNECDSG is a voluntary consortium of medical centers in Maine, New Hampshire, Vermont, and Massachusetts, and maintains a prospective registry of all patients receiving cardiac surgery in the northern New England region.

Dr. Nugent began his presentation on Outcomes Monitoring and Process Analysis for Regional Improvements by briefly discussing some new developments of the NNECDSG. At a recent meeting in Burlington, Vermont, discussions were held about reporting back to institutions their level of appropriateness (that is, doing appropriate operations based on national guidelines). A focus of the meeting was the analysis of stroke after coronary artery bypass graft (CABG) surgery, looking at ACC/AHA Guidelines for CABG Surgery and the data from a new perspective. The group is now looking at patient characteristics across databases (Society of Thoracic Surgeons (STS); New York State; Northern New England).

The NNECDSG did not start out with the aim of outcomes monitoring and process analysis. The group was initially created, in 1987, in response to a letter from the federal Health Care Financing Administration (HCFA, now known as the Centers for Medicare and Medicaid Services, or CMS) regarding the mortality rates of the hospitals. The group started as a defense against what it saw as an incursion on privacy by outside parties. The group exists to develop and exchange information concerning the treatment of cardiovascular disease. It is a regional, voluntary, multidisciplinary group of clinicians, hospital administrators, and health care research personnel – all of whom seek to improve continuously the quality, safety, effectiveness, and cost of medical interventions in cardiovascular disease. The group banded together to use its data to improve the outcomes of its patients and study those outcomes as it did so.

After collecting data for 2 ½ years, the group reported in 1991 that there was a significant variation in mortality rates between institutions in northern New England. This information came on the heels of a paper by John Wennberg, M.D. that looked at the variation in utilization of transurethal resection of the prostate for benign prostate hyperplasia. The feeling was that if there was variation in use of a procedure, there was likely to be variation in the outcome of the procedure. So the group studied CABG. The group found variation ranging from 3 percent to 6 percent or 2 percent to 5.7 percent, depending on whether the mortality data was adjusted or crude. (JAMA 1991; 266:803-809) Initially, there was concern about releasing the data to the public, especially in regard to reporters demanding to know which hospitals had the higher mortality rates. At that time, Dartmouth was the "high-mortality" institution. The reporters, however, allowed the institutions time to start working with the information and early initiatives to improve the mortality rates.

The NNECDSG set up a system for data feedback, providing reports on a regional, medical center and surgeon level. They invested in significant quality improvement training, turning to Donald Berwick, M.D. for guidance and training that included meeting skills and statistical analysis. The focus became to fix the process and to avoid laying blame, and to measure and use the data.

The region had to decide how to improve the processes. The group decided to invest in a very important initiative, a site visitation strategy. The options were to go outside or stay within the region. The decision was made to stay within the region. The group set up benchmarking visitation schedules and put multidisciplinary teams together at every institution to visit every other institution. The two to four hours spent traveling to other institutions provided a rare opportunity to get to know other members of a team. The teams discovered that all facilities were dealing with similar problems.

The data feedback reports placed the observed and expected rates along a time continuum. After two years, a change was seen with mortality rates improving; they dropped 24 percent as the group finished this first period. Every institution improved, the best as well as the worst in the region. (JAMA 1996; 275:841-846) Ghali suggested that the reduction seen in both northern New England and New York State would have happened regardless of quality improvement (QI) efforts, as similar improvement was found in Massachusetts, where there was neither a statewide, organized improvement effort nor dissemination of mortality data. (JAMA 1997; 277:379-382)

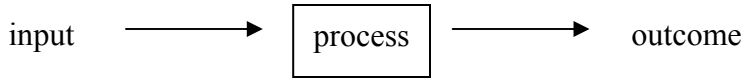
Peterson challenged the conclusion and examined Medicare data on both the total amount of improvement and the ultimate risk-adjusted mortality rate. He found that New York State and northern New England showed both the lowest overall mortality rates as well as the greatest improvements of any other state or region in the country. Peterson concluded that reporting of outcomes, whether voluntary and anonymous (northern New England) or mandatory and public (New York State), coupled with initiatives in quality improvement, is indeed effective in improving mortality rates after CABG. (JACC 1998; 32:993-999)

By 1995, the group had begun to answer the question about how many people were dying following CABG. The group felt that there were two more important questions that it needed to know more about: 1. Who dies following CABG? 2. How do they die following CABG? The group examined the risk of in-hospital death associated with emergency coronary bypass surgery and poor ventricular function. After looking at 31,549 consecutive patients who had surgery between 1992 and 2000, elective cases were found to have a low mortality rate (1-3%), based on their ejection fraction (EF), with the mortality rate of urgent cases increasing proportionately (2-5%), followed by emergency cases with the highest mortality rate (6-12%). The urgent population was defined as patients unable to be discharged from the hospital, but still able to be scheduled for surgery.

Raw numbers showed that most patients were in the elective and urgent category. The actual number of patients dying is greatest in the urgent cases. The highest percentage of all deaths fell in the urgent normal EF category (14.3%), although this is a low risk group. Based on their acuity in terms of preoperative EF, the urgent and elective patients make up about 75% of all deaths. Therefore, the greatest opportunity to have a real impact on quality improvement is for cases with normal EF who require urgent or elective care.

The NNECDSG led a regional retrospective review of CABG deaths in an effort to identify "mode of death." Mode of death is defined as the event that started the chain of events ultimately leading to the death of the patient. It is not the cause of death. The group looked at 4,000 consecutive deaths in the region. The most common mode of death (about 47% of patients) was found to be low cardiac output failure. Other modes of death included neurological, respiratory, dysrhythmia, and hemorrhage. The group further looked at how the surgeon may impact on mode of death. Based on adjusted mortality rates, surgeons in the region were profiled into terciles of risk (high, medium, and low). The study found that the incidence of low cardiac output explains the majority of difference in mortality rate between high risk and low risk surgeons. (Ann Thor Surg 1998; 66:1323-1328.) Fatal heart failure accounted for 80% of the difference in aggregate mortality rates, ranging from 1.9% in lowest surgeon mortality tercile to 4.0% in the highest tercile. Rates of other causes did not differ significantly across surgeon mortality terciles. Differences in rates of fatal heart failure could not be explained by differences in preoperative left ventricular dysfunction or other patient characteristics. That is, most of the difference in observed mortality rates across surgeons is attributable to differences in rates of heart failure.

Dr. Nugent described the diagram below as the take-home message of his talk. The NNECDSG focuses much of its work on looking at the process of care.



First order analysis involves looking at the outcome only, which relies on the input and process. Focusing on the process is considered second order analysis. Being profiled based on outcome alone tells nothing about how to change processes. The NNECDSG began to find process variables within its data set that clinicians could actually have control over and that would lead to a statistically higher likelihood of survival in its patient population.

By analyzing the regional database, four processes were identified that improved the outcomes of patients who had undergone CABG:

1. Aspirin pre CABG
2. IMA utilization
3. Adequacy of beta-blockers
4. Avoidance of anemia on bypass.

Aspirin (Ann Thor Surg 2000; 70: 1986-1990.)
A univariate analysis showed a 27% protective influence of just being on aspirin before surgery. The protective effect increased to 45% using multivariate analysis and correcting for such factors as body surface area and comorbidities. CABG patients using preoperative aspirin were less likely to experience in-hospital mortality. Aspirin use varied across the five centers in 1999-2000, from a low of 54.8 percent to 97.1 percent.

IMA and CABG (Circulation 2001; 103:507-512)
There is evidence that patients having coronary artery bypass graft surgeries with an internal mammary artery (IMA) have better long-term survival. In addition, it was found that IMA grafting has a strong protective effect on perioperative mortality. Adjusted data show that in-hospital mortality decreased from 4.9 percent to 2.2 percent. IMA use across five centers show a small range of 89.3 percent to 96.9 percent, compared to the national average of about 73 percent.

Pre-induction Heart Rate (Fillinger MP et al. accepted for publication in Anesth Analg, 2002)
This process variable came out of the anesthesia subcommittee. In-hospital mortality rate appears to be dependent on heart rate when the patient is rolled into the OR. If the patient's heart rate is allowed to go over 80 beats per minute (bpm), there is a significant increase in mortality (from 1.7 percent to 3.1 or 4.0 percent), even with adjusting for risk factors. The NNECDSG recently began a study to determine whether intervention at the time of surgery with a short-acting beta-blocker has an impact. Currently, three centers are tracking the number of patients found to be tachycardic who are being intervened upon at the time of surgery. Results show a range of 21.8 percent to 45.2 percent usage of beta-blockers.

Lowest Hematocrit on Cardiopulmonary Bypass (CPB) (Ann Thor Surg 2001; 71:769-776)
This process variable came out of the perfusion subcommittee. The NNECDSG wanted to find out what the impact of transfusion rates was on mortality rates in patients having CABG.

Looking at elective patients, the likelihood of getting transfused ranged from 23 percent to 78 percent, depending on the institution. This wide variation suggested that the decision to perform a transfusion was based on the provider, not on the patient. It was found, after adjustment for preoperative differences in patient and disease characteristics, that the lowest hematocrit measured during CPB was significantly associated with increased risk of in-hospital mortality. In-house mortality ranged from 3.9 percent for patients with a lowest hematocrit of less than 19, to 1.6 percent for hematocrit levels above 25. In response to those findings, there was a change in transfusion practices. In 1997, 26.5 percent of cases had a hematocrit less than 20, compared to only 9.2 percent regionally in the year 2000.

The NNECDSG publishes its findings and proselytizes at its meetings, but has no mandate on how centers should react to the findings. It is up to each to decide whether to change practices in light of new data. It is up to the individual cardiac surgeon to decide IMA use, the anesthesiologist to decide treatment of tachycardia in the operating room, the team to decide prospective or later transfusion, and the team or individual cardiologist to decide whether to keep the patient on aspirin.

Overall, there has been a decline in the regional mortality rate of the original five members of the consortium, from approximately 4.5 percent in 1987 to fewer than 2 percent in 2000. This was achieved by conducting data feedback, QI training, and site visits, investigating mode of death, followed by process mapping and identifying process variables. The group has a grant from the American Heart Association (AHA) to specifically look at ways to deal with recognizing, diagnosing and treating low cardiac output syndrome.

Dr. Nugent concluded that understanding processes that determine outcome is critical for improvement, and that outcome reporting can be an effective improvement tool when coupled with process analysis. Large numbers of patients are needed to determine the fine changes when outcomes are already good. That mandates some level of collaboration, cooperation, and trust.

Dr. Nugent rhetorically asked why New York State and STS have not done the same level of process analysis. He reported that there are some unique qualities of the NNECDSG. There is no ambiguity in the purpose of the group – it is to improve outcomes, not to promote one institution over another, or to use that data either for or against an institution. There is no question about ownership and control of the data. The NNECDSG has established a safe place to work and provided a forum for discussion. The NNECDSG typically meets three times a year, usually a Friday afternoon followed by a Saturday morning. The members rotate meetings and travel expenses are funded out-of-pocket.

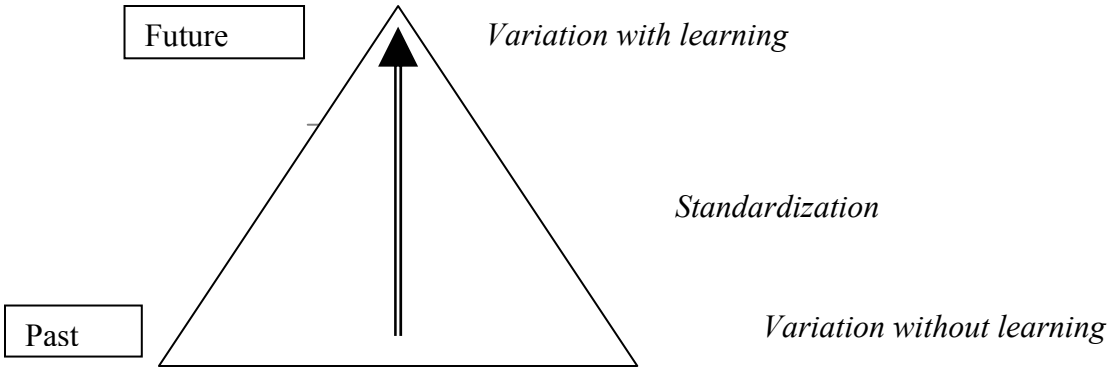
The NNECDSG focuses on three areas: clinical, administrative and academic. The clinical work currently involves data validation. The group validated for the third time its latest 30,000 patients, with a 99.7 percent validation. Mortality is based on in-hospital mortality, rather than 30-day mortality, because it is easier to validate. The group is now reconciling discrepant charts. The group currently has an AHA grant to work on the low output study. There is also a stroke initiative currently in progress. The group has completed a look at the timing of CABG and acute myocardial infarction (AMI) patients, reviewed its balloon utilization collaboration with two centers in Canada, and established a patient safety committee.

On the administrative side, there are three new members and now nine hospitals involved in the regional collaborative, with no political agenda. There is an agreed-upon format for sharing outcome data with third-party payers and other interested parties. This collaboration was between the executive committee of the NNECDSG and member hospitals' administrators. The outcome data cannot be used to promote one hospital as better than another, if there is no significant difference. All data are HIPAA compliant. Every hospital has informed consent and has gone through an institutional review board (IRB) procedure.

Academically, the NNECDSG has over 150,000 consecutive cases (including PCIs) and is observing the 11th anniversary of its first publication. There have been over 80 publications in various journals, including JAMA and JACC.

The NNECDSG represents a regional clinical collaboration. Dr. Nugent covered some points on how to start such a group. It is important to recognize that this is not recreational data collection, and that a little good data is better than a lot of bad data (i.e., high quality, low quantity). The key to maintaining a data collection group is to build credibility and trust. One way to achieve this is through publishing work in journals. The NNECDSG does not publish a paper unless there is at least one author from each organization in the consortium. Academics need to take a leading role in this. Finally, it is important to ensure that the process is working. Methods to know if it is working include: clinical use of data precludes "gaming" strategies, measurable practice changes occur based on data collected, and the group becomes equally concerned about outcomes for all hospitals. The nine hospitals currently have a regional CABG mortality rate of 1.7 percent; the difference is insignificant across all hospitals.

Dr. Nugent stated that a Rockwellian view of medicine is required, where the institutions need to work together as a team. It is a complex environment, working with a multidisciplinary group. He believes that the future will move to variation with learning.



Dr. Scheuer opened the floor for questions. Luis Mispireta, M.D. commenced the questions by confirming that the data presented was only for CABG. Dr. Nugent replied that the data in his presentation was for CABG only, but data is also available for valve and PCI procedures.

Dr. Mispireta further asked about the difference between NNECDSG and STS. Dr. Nugent responded by saying that one major difference was regional versus national. There are also some small differences between the variables collected. Robert H. Jones looked at the variables of the two data collection groups, and found that the key variables that really determine 90 percent of the difference are the same. Dr. Nugent stressed that the difference is how the tool is used, rather than the tool (database) itself. The STS is focused nationally, while Dr. Nugent believes that you need to look regionally to make a difference.

Dr. Scheuer asked how the group assures uniformity and accuracy in the completion of the data set, and who pays for the data set. Dr. Nugent noted that the NNECDSG chose to use in-hospital mortality as an end point, rather than 30-day mortality as used by STS, because in-hospital mortality is easier to validate using administrative databases. However, administrative databases are difficult to risk stratify. Dr. Scheuer inquired about how ejection fraction and hematocrit are collected. Dr. Nugent informed the group that they are collected prospectively. Data is collected in medical records. Although every institution handles data collection differently, it is possible to have uniform reporting. Dr. Nugent added that the subjective interpretation is the place where the data tends to be the softest.

Dr. Nugent went on to say that it costs $400,000 to operate the consortium each year. Fifty percent of this is supported through grants, while the remaining 50 percent comes from dues. Institutions often include the dues in the budget for quality assurance because reports can go directly to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The consortium is a non-profit group, employing 2.5 analysts and 0.5 of an epidemiologist.

Donald Dembo, M.D. acknowledged the difficulty in validating mortality at 30 days, and asked about using quality of life markers for morbidity. Dr. Nugent reported that the SF 36 has been used in several situations, but is difficult to operationalize. Other functional health tools have been considered.

Dr. Clark asked how the NNECDSG built in the National Guidelines (ACC/AHA Guidelines for CABG Surgery) in order to determine appropriateness. Dr. Nugent reported that the Classes I, II, and III were used, as well as emergency versus non-urgent procedures, EF, and number of diseased vessels. Sometimes it was necessary to look at surrogates to determine the appropriateness of the treatment. Dr. Nugent said that he would like to see the multiple data sets consider changing the definitions of variables to match the guidelines.

Dr. Clark asked if the administration has the same “warmth” about the regional approach as the physicians. Dr. Nugent replied by recounting a situation he recently experienced. He was speaking to a CEO, whose hospital was recently listed as number seven in mortality rates. The CEO asked Dr. Nugent how he could get his hospital to be number one. In fact, the first hospital listed was ranked highest among the hospitals, then the next hospitals listed from two to seven were all statistically the same, i.e., significantly not different. The discussion indicated that CEOs cannot talk to other CEOs about this issue, however, physicians can talk to other physicians about how to better their practices and be number one.

William Baumgartner, M.D. started by congratulating Dr. Nugent on the great work done by the NNECDSG. He asked whether it was difficult to reproduce the process of the group, and how the risk algorithm is accomplished. Dr. Nugent replied by saying that the data is risk stratified, using logistical regressions to determine variables and then appropriate weight. The main variables concentrated on to date have been in-hospital mortality and risk by EF and risk of low cardiac output. The NNECDSG created a Pocket Card Chart to assist in identifying risk, where physicians can circle appropriate risks, add up the weights and enter a value in the medical charts. This risk profile is part of the preoperative workup for all patients.

Dr. Mispireta commented on the tremendous infrastructure that must be required to set up such a service, and wondered if the NNECDSG has considered providing a service for other entities. Dr. Nugent said that the group has been approached before, but the infrastructure cannot support much more than the group at this time. Becoming a national warehouse would change the focus of the group. Dr. Nugent went on to say that the group has begun to move away from being a discussion group with presentations, to being more of an academic society with less productivity.

Steve Lowenthal, M.D. applauded the efforts of the NNECDSG, and wondered how it would work if hospitals were all located within 20 miles. Dr. Nugent was not sure if it would work as well, and thought it would be essential to be explicit about how the data would be used and to build credibility. The NNECDSG has a great research director, Gerry O'Connor, who does great statistical modeling and has managed to collect complete sequential regional data.

Eugene Passamani, M.D. noted that the group has been formed for over 10 years now, and wondered whether the group would do anything different if it were starting today. Dr. Nugent said the only thing the group may do differently is to have an electronic interface; it would not change anything in the format of the organization. However, Dr. Nugent feels that the group may need to start changing certain aspects as the focus on CABG becomes outdated. New areas of focus include PCI variables, such as groin hematoma, where the focus is not on mortality as an outcome.

Dr. Passamani also inquired about the center that recorded a low preoperative aspirin use (54%). Dr. Nugent replied that the data are descriptive, not prescriptive.

Dr. Clark inquired about the implications of the Freedom of Information Act on the data. Dr. Nugent said that the data is the group's data and is protected under peer review provisions. No one has challenged that. Dr. Nugent stressed the importance of publishing the data.

John Laschinger, M.D. asked how the database is compiled. Dr. Nugent said that the perfusionist fills out most of the data using a check-off list.

James Brown, M.D. asked Dr. Nugent for additional information about Gerry O'Connor, and what Dr. Nugent would do if NNECDSG were transplanted to Baltimore, with hospitals collecting STS data.

Dr. Nugent answered by stating that Gerry O'Connor is an epidemiologist who has remarkable consensus-building skills, statistical credibility, and considerable knowledge. The NNECDSG pays for and owns its data. Other hospitals are also collecting the same information in parallel. Dr. Nugent noted that the New York State system is set up so that its data is public, which can result in delays in data reports, when the hospitals could be acting to fix problems quicker. Finally, STS data is a good tool. Re-invent the tool only when necessary. Dr. Nugent reiterated that what is important is how the organization uses the tool, not the tool it uses.

Dr. Scheuer thanked Dr. Nugent for his very helpful presentation and for sharing his experience of working with the NNECDSG.

5. Subcommittee Reports and Discussion

Dr. Scheuer asked the chairman of each subcommittee to report on its group.

Quality Measurement and Data Reporting

Dr. Mispireta reported that he has had several telephone conferences regarding cardiac surgery quality and data issues. He hopes that the final concepts for the surgical side of the subcommittee's charge will be recommended at the next meeting of the Steering Committee. After finalization of the surgical data collection, the directors of the cardiac catheterization laboratories are expected to discuss their data collection. Dr. Mispireta noted that there are nine surgical centers, and a larger number of cath labs.

Long Term Issues

Dr. Passamani reported on the progress of the Long Term Issues Subcommittee. At the first meeting, Jeanette Jenkins presented background material on the Healthy People 2010 project. Edward Kasper, M.D. presented information on congestive heart failure (CHF). Tom Aversano, M.D. presented information on patient outcomes clinical trials related to CHF. Dr. Passamani said that CHF will have a growing importance in hospital treatment, and might be an area to focus on for process improvement. Drs. Kasper and Aversano each presented approaches on a regional level.

Dr. Scheuer asked if there had been any discussion of use of the various guidelines in the process. Dr. Passamani said that the subcommittee had not focused on the guidelines as such in its discussions of a cardiovascular disease model.

Diane Bild, M.D., M.P.H., of the National Heart, Lung, and Blood Institute (NHLBI), will be discussing the detection of sub-clinical coronary artery disease at the next meeting. Her presentation will include current methods and future prospects for detecting heart disease early, before it produces symptoms.

At the meetings, there has been some disagreement on the most cost-effective focus: primary or secondary prevention. However, some felt that it is hard to persuade well people to change and adopt healthier lifestyles. Dr. Passamani said that with a focus on CHF, it will be possible to identify subclinical disease, and target unserved populations, for example, minorities and those with low socioeconomic status (SES).

Dr. Passamani anticipates that the subcommittee will require a few more meetings before being able to put forward a recommendation to the Steering Committee.

Inter-Hospital Transport

Ms. Barclay reported on behalf of Jeffrey Jones, M.D., the Chairman of the Inter-Hospital Transport Subcommittee. The subcommittee held its first meeting on August 22nd. The subcommittee discussed its charge, structure, and timetable. Cheryl Y. Bowen, M.S., M.A., R.N., Director of Commercial Ambulance Licensing and Regulation for the Maryland Institute for Emergency Medical Services Systems, gave a presentation on the Maryland Neonatal Intensive Care Transport System. The subcommittee also heard information about the development of a private inter-hospital transport system by three hospitals in the Baltimore City/Baltimore County area that provide cardiac surgery and interventional cardiology services. At the second meeting, members looked at different transport systems in place across the state and region, and discussed the type of data needed to establish reasonable goals on how quickly people are transported.

Dr. Scheuer commented on the transport trial for emergency PCI, which had to be stopped because outcome was so significantly in favor of emergency PCI versus thrombolytics. Robert Bass, M.D. noted that transport by ambulance to an interventional center could work like that of the trauma system. There is potential to have information available to make decisions.

Interventional Cardiology

Ms. Barclay reported on behalf of the chairman, David O. Williams, M.D., Director of the Cardiovascular Laboratory and Interventional Cardiology at Rhode Island Hospital in Providence, Rhode Island. The Interventional Cardiology Subcommittee held its first meeting on September 4th, at which the members discussed the charge, structure, and timetable of the subcommittee, and a proposed work plan and process. The subcommittee approved the preparation of a "state of the evidence" paper as part of its process. Dr. Aversano, Director of the Atlantic C-PORT, is scheduled to discuss the results of the randomized trial comparing primary angioplasty with thrombolytic therapy at hospitals without on-site cardiac surgery, and the ongoing primary angioplasty registry established after the trial closed, at the next meeting on October 16th.

Dr. Dembo spoke about the impact of transport and the process of mechanical intervention versus thrombolytics. It appears obvious that the State should be triaging to centers that are capable of PCI, in a similar fashion to trauma centers. Trauma centers financially lose money; however, this is not the case for cardiac care. Dr. Bass reported that the trauma system in Maryland has been in operation for over 30 years, with other states having a system for not as long. Hospitals are concerned about losing cases and money.

Dr. Scheuer asked about the development of local PCI (i.e., PCI with no surgical back-up) and transport to centers, and how these can be integrated. He said that the two processes do not have to be adversarial. Dr. Misperita stated that diagnosis is the key indicator for where patients go. Dr. Passamani commented that stroke has the same issues; in the long run, the State wants patients to show up where the best care can be provided. This can be achieved by using a

systematic response. Dr. Passamani stated that these services might be more expensive for some hospitals to take on.

Dr. Bass said that MIEMSS is looking at the triage of cardiac patients. Hospitals will need to make a commitment to see a patient in a stated timeframe. He noted, however, that the data on stroke is softer than that on cardiac. A systematic approach may be a way off for stroke. In response to a question concerning the issues faced by trauma centers around the country, Dr. Bass said that in Maryland some hospital administrators think that trauma centers are advantageous to their hospital, although they do bring in nonpaying patients.

6. Other Business

There was no other business.

7. Adjournment

The meeting adjourned at 7:20 p.m.

Summary of the Meeting
of the
Advisory Committee on Outcome Assessment in Cardiovascular Care

December 17, 2002
4160 Patterson Avenue, Conference Room 100
Baltimore, Maryland

Committee Members Present
James Scheuer, M.D., Chairman
Robert Bass, M.D.
William A. Baumgartner, M.D.
Scott Friedman, M.D.
Luis Mispireta, M.D.
Eugene R. Passamani, M.D.

Commission Staff Present
Barbara G. McLean
Pamela W. Barclay
Bridget Glazebrook
Valerie McRae
Susan Panek
Debbie Rajca
Dolores Sands

Members of the Public Present
Vanessa Aburn, University of Maryland Hospital
Sean Flanagan, St. Joseph Medical Center
Gary Jones, Shore Health System
Jack Neil, Anne Arundel Medical Center
Vanessa Purnell, MedStar Health

1. Call to Order

James Scheuer, M.D. called the meeting to order at 6:10 p.m.

2. Approval of the Minutes of the Joint Meeting of the Steering Committee and Quality Measurement and Data Reporting Subcommittee (October 2, 2002)

On the motion of Eugene R. Passamani, M.D., which was seconded by Luis Mispireta, M.D., the minutes of the October 2nd Steering Committee meeting were approved.

3. Subcommittee Reports and Discussion

Dr. Scheuer began by setting the timetable for the work of the Advisory Committee on Outcome Assessment in Cardiovascular Care. The goal of the Advisory Committee is to complete its process and report by the end of April 2003. A number of steps are required to accomplish this goal:

- Each subcommittee will meet in January 2003.
- The Steering Committee will meet in early February 2003 to review the progress of the subcommittees.

- Each subcommittee will submit a final report to the Steering Committee by March 1, 2003.
- In March, the Steering Committee will discuss and consider suggestions on the draft of the final report of the Advisory Committee. The Advisory Committee will complete the final report by April 30, 2003.

Dr. Scheuer noted that a newly elected governor and a new legislative session commence in Maryland in January 2003. He asked Barbara McLean to comment on upcoming events. Ms. McLean stated there will be legislation introduced on subjects that the Advisory Committee is considering. There will be new legislators in the House and Senate, who will be new to the process and issues being debated. It is important that the Advisory Committee on Outcome Assessment in Cardiovascular Care be able to report its progress if the legislative committees hold public hearings on the proposed legislation. Dr. Mispireta inquired whether members of the Advisory Committee will have any opportunity to lobby, speak, or otherwise help with the legislative process. Ms. McLean replied that such participation would be helpful, and that the subcommittee chairs may be asked to brief legislators.

Next, Dr. Scheuer invited each chairman of the subcommittees to present subcommittee's report. He noted that two of the chairs were present.

Quality Measurement and Data Reporting Subcommittee

Dr. Mispireta, Chairman, presented the Quality Measurement and Data Reporting Subcommittee report. The subcommittee has held four meetings to date. A fifth meeting, at which the subcommittee planned to discuss recommendations, was cancelled due to poor weather and rescheduled for January 7, 2003. Dr. Mispireta noted that the efforts to date of the subcommittee have been directed towards cardiac surgery, which will form a template to be used for interventional cardiology as well. He stated that the subcommittee has defined the basic process. The Cardiac Surgery Data Work Group reviewed and discussed options, and reached a consensus on the approach for cardiac surgery services. All directors of the cardiac surgery programs in Maryland have concurred with the recommended approach; however, the subcommittee must approve the work group's recommendations before presenting them to the Steering Committee. There has been a consensus by the Cardiac Surgery Data Work Group on the following:

Scope – include CABG and valve procedures, and exclude procedures for congenital heart defects.

Data Elements – use the STS (Society of Thoracic Surgeons) Adult Cardiac Surgery Database as the core data set. Data elements may be added to address specific issues or needs identified by Maryland programs.

Data Management – outsource the data processing and management. Currently, all Maryland cardiac surgery programs are involved with STS. The Duke Clinical Research Institute (DCRI) harvests and provides data analysis twice a year. It is possible to work with

DCRI to receive specialized reports, including a more regular quarterly report. There will be an additional cost associated with this; however, the amount is unknown currently.

Organizational Structure and Governance – establish an independent group, representative of all Maryland cardiac surgery programs, to examine the data and make decisions based on the data. It was unanimously decided that the group will be a permanent workgroup, although the individuals involved may change, and will include cardiac surgeons, as well as anesthesiologists, perfusionists, and other health professionals who are key to the process and outcomes.

Submission of Data – provide for voluntary participation, with close monitoring. If low involvement occurs, the process may become mandatory.

Access to Data – provide aggregate data to MHCC. The report to MHCC would become public information. Raw, unaggregated data would be protected from public disclosure under the medical review statute, so that the proceeding records and files remain confidential and not discoverable or admissible in evidence.

Funding – use two sources of funds to cover the cost of the data collection and reporting. In addition to costs absorbed by participating institutions, the consortium will apply for grants.

Dr. Scheuer thanked Dr. Mispireta for his report, and inquired about the process of the quality measurement and data reporting for interventional cardiology, and whether a work group has been assigned yet. Dr. Mispireta replied that he expects the cardiac catheterization lab directors to have a teleconference after the holiday. Prior to the meeting, he will send the process/concept recommended by the Cardiac Surgery Data Work Group. The lab directors will consider the use of the American College of Cardiology (ACC) database, in place of the STS database.

Dr. Passamani inquired whether rotating peer review site visits had been discussed as a component of addressing quality issues. Dr. Mispireta said that this has been discussed as a method to learn and share best practices, and would be implemented ideally. Dr. Mispireta added that this type of process would be more beneficial after receiving the first round of data, when it would be known what sites and areas to focus on, e.g., stroke or infection. Dr. Scheuer noted that such visits, as discussed by Dr. William Nugent in a previous meeting, have been successfully used in Northern New England, where there is not a lot of close competition, due to the location of the hospitals, and he wondered if they would pose a problem in Maryland, where hospitals are closer and perhaps more competitive. Dr. Mispireta did not expect that to be a potential problem. William A. Baumgartner, M.D. said that he, like Dr. Mispireta, is very optimistic that the process will work in Maryland. A bona fide group of quality caregivers will be set up to institute the process, and that it would be in the physicians' interest to make it work.

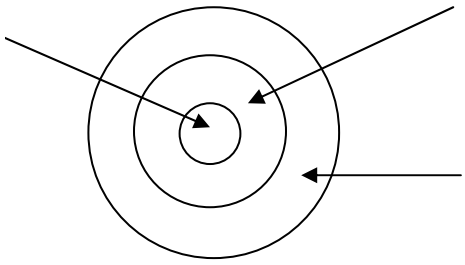
Long Term Issues Subcommittee

Dr. Passamani, Chairman, presented the Long Term Issues Subcommittee report. The subcommittee has held five meetings to date. The charge provided by the Steering Committee to

the subcommittee was initially interpreted differently by various subcommittee members. The process used to achieve consensus was to assess the current state of cardiac health, then focus on the desired state and how best to achieve that. The subcommittee meetings consisted of several presentations by experts in various areas to gain an understanding of potential areas of focus. Edward Kasper, M.D. and Tom Aversano, M.D. provided presentations on congestive heart failure (CHF), which indicated that the incidence is going to increase. There is good data on the therapies available; however, there is inconsistent application of treatment, especially with compliance after hospitalization. Drs. Kasper and Aversano addressed a case or care management approach. CHF affects minority groups at a higher rate, which raises the issue of access to care. Diane Becker, ScD., M.P.H., spoke to the group about her work with African-American groups across Maryland, in particular, using churches to great advantage to bridge the gap between the medical community and poor African-American patients.

Some discussions were held throughout the subcommittee meetings on addressing risk factor treatment (primary prevention). Dr. Passamani reported that preventative care is difficult to implement, due to the difficulty in motivating well patients to change lifestyle behaviors. He referred to the concentric circle model, where the inner circle represents high-risk individuals with clinically evident disease (e.g., high blood pressure, diabetes), and the outer circles represent individuals in healthier states.

Clinical model - focuses on clearly identifying, intervening and managing disease as a part of promoting health.



Lifestyle or behavioral approach - deals with managing lifestyle practices that may be health risk factors, such as diet, exercise, and stress.

Social-environmental model - looks to the broad determinants of health, such as the physical environment and isolation.

Other presentations to the subcommittee included Diane Bild, M.D., MPH, of the NIH, who spoke about the Multi-Ethnic Study of Atherosclerosis (MESA) and the noninvasive techniques available to identify subclinical coronary artery disease; and Lisa Myers, R.N., M.S., of MIEMSS, spoke about Automated External Defibrillators (AEDs).

Dr. Passamani noted that the subcommittee focused on the practical approaches that could be achieved through the process provided. Some areas discussed are important (for example, 'Why can't drugs be cheaper?'), but were not further investigated.

Dr. Mispireta inquired whether the subcommittee considered the 'lost opportunity' when patients are discharged from the hospital and return to their family physicians, and whether educational materials could be distributed to primary care physicians to provide to patients. Dr. Passamani said that he thought this was already well taken care of for cardiac care, through the ACC's Guidelines Applied in Practice (GAP) program. In addition, the American Heart Association has produced "Get With The Guidelines."

Dr. Scheuer commented that studies involving HIV/AIDS have examined patient barriers to drug compliance and that these studies may be worthwhile to look into. He added that non-compliance with treatment for hypertension is extremely important, and improving compliance could lower readmission rates and reduce costs.

Referring to the presentations of Drs. Kasper and Aversano on heart failure, Dr. Passamani suggested that the Centers for Medicare and Medicaid Services may be a source of research funds.

Inter-Hospital Transport Subcommittee

Pamela Barclay presented the Inter-Hospital Transport Subcommittee report on behalf of Jeffrey Jones, M.D., Chairman. Ms. Barclay reported that the subcommittee has met three times. In its information-gathering phase, the subcommittee has had a number of presentations from experts, including:

- Cheryl Bowen, M.S., M.A., R.N., MIEMSS, who outlined the mechanism in place for neonatal intensive care transport in Maryland. Ms. Bowen also presented information on MIEMSS medical protocols governing the scope of practice for EMS providers of Maryland.
- A group of hospitals located within Baltimore discussed the development of a private inter-hospital transport system to facilitate patient transfers between hospitals for cardiac surgery and interventional cardiology services.
- MedStar, STAT MedEvac, and Mid-Atlantic Region for Rural/Metro Corporation provided an overview of their air and ground transport services in Maryland and adjacent states.

At its next meeting, the subcommittee will address the issue of reimbursements for transports.

Dr. Scheuer inquired whether discussions were held about ideal or maximum transport times for patients in need of acute cardiac care. Ms. Barclay replied that the subcommittee talked about tracking the data and creating a data set for each component involved in transport. With the data, the members expect to determine the length of time for transports, and then benchmark the results against the literature.

Dr. Scheuer suggested that recommendations for transport times could be included, as well as goals for performances. Dr. Mispireta stated that the consortium of hospitals in the Baltimore area has been collecting data and looking at how times can be improved. The hospitals found that the largest saving in time can be made at the institution transferring the patient out (as opposed to the time between the call and arrival). Intravenous (IV) lines often cause the most delay in transporting patients. This may be resolved, for example, by giving a bolus of heparin to eliminate the line used for heparin drip. The consortium may provide other protocols to assist in reducing transport time. Dr. Scheuer said that such issues have been dealt with by hospitals with primary angioplasty programs or thrombolysis programs. Most hospitals track door-to-needle or door-to-cath time. Dr. Scheuer mentioned the Danish Myocardial

Infarction Study (DANAMI) and Cardiovascular Patient Outcomes Research Team (C-PORT) trials. Dr. Mispireta expressed concern over the transport of patients from the C-PORT hospital to the cardiac surgery facility, and the possible delay at both ends. Dr. Passamani felt that the real issue is the mismatch between the needs of the patient and the ability of the hospital to meet those needs. He continued by saying that most of the delay comes from finding a physician at the accepting hospital, because a patient can not be transferred from emergency department (ED) to ED (because of EMTALA). Robert Bass, M.D. concurred and suggested that there are some creative steps that could be taken to eliminate this problem. One method would be to create regional systems of care with a one-stop call to a triage center that would direct the patient and notify the hospital.

Scott Friedman, M.D. noted that the DANAMI II approach had been successful, where the ambulance emergency team remained with the patient on line, until the ED cardiologist determined if the patient would need to be transferred to a hospital with invasive cath labs in order to perform an angioplasty. Dr. Bass expressed some concern over this practice, because it is crucial to keep an ambulance in service, and this method has the potential to tie up the ambulance team, especially when it is not known which patients will require transfer. Dr. Friedman replied that the method was found to be efficient in Denmark. Dr. Bass described a two-pronged approach: (1) pre-hospital triage (take the patient directly to a facility that can handle the patient's needs), and (2) a regional system to route patients and reduce time. Pre-hospital triage is an issue that has already been fought with trauma care. The regional system has a number of political overtones. MIEMSS is looking at these issues with regard to stroke cases. Dr. Scheuer pointed out that successful inter-hospital transport is an issue of not only moving the patient to a hospital, but making sure that particular processes occur once the patient arrives.

Dr. Baumgartner inquired about the reimbursement issue of inter-hospital transport. Ms. Barclay stated that frequently there is under- or zero reimbursement provided. She noted that moving patients from home to hospital results in no difficulty for reimbursements because of a public system for such transports; however, moving patients from hospital to hospital does present difficulty. Dr. Baumgartner inquired whether a legislative change could alter this. Ms. Barclay replied that subcommittee discussions have not progressed that far. She said that funding would be needed for a regional system. Dr. Bass indicated that the cardiac care transport could be potentially built parallel to the trauma care system. It would involve additional work, such as adding cardiac to the medical protocols, but could be achieved. One factor is that HMOs might balk. Dr. Friedman noted that the selectivity of insurance companies may slow down the process and increase transfer time.

Dr. Passamani commented that the true cost of transporting a patient from home to hospital is more costly than transporting hospital to hospital, because of the high rate of chest pain unrelated to cardiac events. Dr. Bass reported that out of approximately 50,000 annual calls for chest pain, about 5,000 patients may have an acute coronary syndrome.

Interventional Cardiology Subcommittee

Pamela Barclay presented the Interventional Cardiology Subcommittee report on behalf of David O. Williams, M.D., Chairman. Ms. Barclay reported that the subcommittee has met twice. Thomas Aversano, M.D. presented the results and experiences of the C-PORT trial and registry, and provided the opportunity for an open discussion. The next meeting is planned for January 27, 2003, where discussions on primary and elective angioplasty will be held.

Dr. Scheuer noted that Dr. Williams has organized a committee to produce a state-of-the-evidence report. The C-PORT results have created much discussion across the country about non-emergent angioplasty and interventional programs. The reaction to the results has been that if hospitals are capable of performing emergent angioplasties on sicker patients successfully, they should also be capable of performing non-emergent angioplasties on more chronic patients without back-up. In response, Dr. Passamani made two points: (1) most primary angioplasty involves a single vessel that is already closed, and it is hard to make a closed artery worse; and (2) elective angioplasty is performed in much larger, concentrated places, where practitioners have the experience of doing a high volume of cases. Dr. Scheuer stated that there is logic in saying that the more cases a well-practiced team does may improve the outcome of primary and elective angioplasties. He said that the subcommittee must address this issue aggressively, particularly with regard to consideration of a pilot project for certain groups of elective angioplasty patients.

4. Other Business

Dr. Scheuer re-iterated the goals and timelines set for the Steering Committee and subcommittees.

5. Adjournment

The meeting adjourned at 7:05 p.m.

Summary of the Meeting
of the
Advisory Committee on Outcome Assessment in Cardiovascular Care

March 26, 2003
4160 Patterson Avenue, Conference Room 100
Baltimore, Maryland

Committee Members Present
James Scheuer, M.D., Chairman
Robert Bass, M.D.
William A. Baumgartner, M.D.
Bartley Griffith, M.D.
Hilary T. O'Herlihy, M.D.
Sidney C. Smith, M.D. (by telephone)

Commission Staff Present
Barbara G. McLean
Pamela W. Barclay
Bridget Glazebrook
Valerie McRae
Susan Panek
Debbie Rajca
Dolores Sands

Committee Members Absent
Luther T. Clark, M.D.
Donald H. Dembo, M.D.
James L. Field, D.B.A.
Scott Friedman, M.D.
Jeffrey D. Jones, M.D.
Steve B. Lowenthal, M.D.
Thom Mayer, M.D.
Mark Midei, M.D.
Luis Mispireta, M.D.
Eugene R. Passamani, M.D.
Nelson J. Sabatini (ex-officio)
David O. Williams, M.D.

Members of the Public Present
Vanessa Aburn, Union Memorial Hospital
Vanessa Purnell, MedStar Health

1. Call to Order

James Scheuer, M.D. called the meeting to order at 6:10 p.m.

2. Approval of the Minutes of the Previous Steering Committee Meeting (December 17, 2002)

On the motion of William A. Baumgartner, M.D., which was seconded by Bartley Griffith, M.D., the minutes of the December 17th meeting were approved.

3. Subcommittee Reports

Dr. Scheuer prefaced the discussions of the subcommittee reports by stating that the initial process of the Advisory Committee on Outcome Assessment in Cardiovascular Care is coming to an end. He stated that the subcommittee reports need to be finalized before being reported to the Steering Committee and presented to the Commission. He encouraged comments and discussions on the draft recommendations. Dr. Scheuer noted that there were no subcommittee chairmen present.

Interventional Cardiology Subcommittee

Dr. Scheuer noted that there had been extensive discussions held on elective angioplasty, as documented by the minutes; however, this was not yet reflected in the draft report. Currently, the report focuses on acute ST-segment elevation myocardial infarction (MI). He noted that the subcommittee would be meeting again on April 14, 2003, followed by a Steering Committee meeting. At that time, the draft recommendations for elective angioplasty will be considered. Dr. Baumgartner commented that primary angioplasty is less controversial than elective angioplasty.

Dr. Scheuer expressed some concern about the impact of the Institutional Resources criteria on the number of programs in Maryland who could provide primary angioplasty. Pamela Barclay stated that the criteria were based on the C-PORT experience and what other places in the nation are currently implementing, such as Boston. Initially, a criterion requiring a diagnostic load of 500 cases/year was included; however, the subcommittee decided to use the basis of 80 ST-segment elevation MI cases (documented from requests for thrombolytic agents) based on the C-PORT experience.

Dr. Scheuer asked about the number of hospitals operating a 24/7 catheterization laboratory. Ms. Barclay clarified that C-PORT hospitals are operating on a 24-hour basis, although there may be a hospital or two that only operates 9-5. Dr. Baumgartner added that hospitals might not have a cath team ready in the hospital 24/7, but have a mechanism to have the team in position to reach the goal of a door-to-balloon time within 120 minutes.

Robert Bass, M.D. stated that the Maryland Institute for Emergency Medical Services Systems (MIEMSS) currently writes protocols on a statewide basis for the designation of trauma centers requiring that they are in operation 24/7. He suggested that the same could be arranged for cardiac services. Dr. Bass expressed some concern about the wording on page two of the draft report, under "Pre-hospital management of acute ST-segment elevation myocardial infarction." He stated that MIEMSS would be able to promulgate new regulations to identify centers; however, the protocols would need to be different in rural areas. It may not be feasible to direct patients to the "nearest" PCI hospital with cardiac surgery backup on-site in rural areas. Dr. Baumgartner pointed out the provision in the draft that requires the time to treat not increase. Dr. Scheuer agreed that it would be helpful to clarify the use of nearest PCI hospitals. Dr. Bass said that it would be necessary to recognize hospitals that could provide the service, and he offered to help craft the statements in the draft report and promulgate regulations. Ms. Barclay

inquired if it was possible to rewrite that section prior to the April 14th meeting. Dr. Bass agreed.

Pre-Hospital Management (page 2 of draft report) - Revise the last two statements to clarify the recommendations.

Dr. Griffith stated that it was important to address the issues concerning angioplasty with the evidence that is available, and not to expand services based on the demands of hospital administrators. Dr. Bass expressed another concern that EMS may overwhelm facilities in some regions, in particular, within the Baltimore and Washington, D.C. regions. He stated that 45,000 to 50,000 transports occur annually for chest pain, and about 10 percent are actually acute ST-segment elevation MIs. These chest pain calls often come in clusters. He stated that some flexibility is required in the system; if there is a backup of cases and the cath labs are full, it will be necessary to transport patients to the next center. It will also be crucial to be able to monitor the hospital activity. With the trauma system, MIEMSS knows when a center is full and diverts the patient elsewhere.

Ms. Barclay inquired about the use of 12-lead electrocardiography (ECG) as a tool to assist in identifying cardiac events in the field (pre-hospital), and how well that program is dispersed in the state. Dr. Bass reported that MIEMSS provides about $500,000 per year in grants for defibrillators. He will obtain information about the availability of 12-lead ECGs across the state. Dr. Bass stated that presently there is a protocol in place requiring chest pain patients to be transported to the closest emergency department. In the future, it may be feasible with the use of 12-lead ECGs to call the results through to the base station physician, and bypass the nearest hospital and transport the patient directly to a designated chest pain or cardiac center, if appropriate. Dr. Scheuer inquired if it was possible to transmit the 12-lead ECG report to a cath lab. Dr. Bass confirmed that there is capability to transmit the data via radio; however, there is a cost involved, and additional training would be required. Dr. Baumgartner commented that it is not essential to send the 12-lead ECG ahead of time to perform triage. Dr. Scheuer disagreed, saying that if the technology was available, it should be utilized in deciding to call in a team 24/7. Dr. Bass said that there was study data available on the sensitivity and specificity of the use of 12-lead ECGs (for example, occasional false positives). He added that the agencies involved can work out these issues if they have discretion.

Dr. Scheuer recognized a public comment by Vanessa Aburn, Union Memorial Hospital, who recalled that interventional cardiologists at a subcommittee meeting had expressed concern about triaging patients to C-PORT hospitals. She reported that the cardiologists are prepared to accept primary angioplasty patients from their own Emergency Department, but the system would be strained if patients from outside were transported to C-PORT hospitals.

Dr. Baumgartner inquired about the current number of C-PORT hospitals and the number of hospitals that might be added. Ms. Barclay reported that there are currently nine hospitals participating in the C-PORT registry (Anne Arundel Medical Center, Bayview Medical Center, Eastern Memorial Hospital, Holy Cross Hospital, North Arundel Hospital, St. Agnes, Shady Grove Adventist Hospital, Southern Maryland Hospital Center, and Suburban); however, this number could potentially increase. Hospitals participating in C-PORT must commit a significant

amount of resources. Hospitals generally want to get involved with the project, although they become cautious when they are made aware of the level of institutional commitment required.

Quality Measurement and Data Reporting Subcommittee

Dr. Scheuer noted that the draft report of the Quality Measurement and Data Reporting Subcommittee is concise and restricted to cardiac surgery.

Dr. Baumgartner inquired about the status of House Bill 164 -- Medical Review Committees. Barbara McLean reported that HB164 had been moved out of the Maryland House of Delegates and into the Senate. Dr. Baumgartner inquired whether the bill provides the protection required for a Medical Review Committee. Ms. McLean stated that HB164 was drafted for the creation of a Maryland Patient Safety Center, in anticipation of a grant from the Agency for Healthcare Research and Quality (AHRQ). She noted that if the AHRQ grant is not forthcoming, it would be possible for the Commission to designate another entity as the Patient Safety Center; that is, the cardiac consortium could potentially house the data collected under this provision. Dr. Scheuer wondered if this protection could be challenged several years later. Ms. McLean stated that she would get the Assistant Attorneys General to confirm the protection. Dr. Baumgartner said that he has asked the Johns Hopkins attorneys to work with the Assistant Attorneys General.

Dr. Baumgartner noted that the draft report states that the consortium will start with voluntary reporting of data; however, it seems that it may move towards being mandatory. He commented that virtually every cardiac surgery program in Maryland agreed to participate.

Dr. Scheuer expressed concern that the draft report addresses only cardiac surgery data reporting and questioned if there should be a future goal to expand to other areas, such as, interventional cardiology and implantable cardioverter defibrillators (ICDs). The subcommittee recommendations can be considered the initial report with the goal to expand to other areas. Dr. Baumgartner reported that there has been some inertia on the interventional side of the data reporting subcommittee. Ms. Barclay reported that Dr. Luis Mispireta, chairman of the subcommittee, had tried to organize a meeting of the catheterization lab directors; however, there was low attendance. It may be possible to connect with the directors through the Interventional Subcommittee. Dr. Scheuer restated that the final report would need to mention the goal to expand quality measurement and data reporting to additional areas of interest.

Introduction (page 1) – Revise to mention the goal to address interventional cardiology.

Long Term Issues Subcommittee

Dr. Scheuer noted that there were no Long Term Issues Subcommittee members present.

Dr. Scheuer commented that the minutes of the subcommittee contain extensive discussion of risk factor awareness and prevention; however, the discussion does not appear in the draft report. Ms. Barclay stated that it was difficult to keep the report inclusive and focused at the same time. She noted that the draft report does address high blood pressure, obesity, and

diabetes; however, she will take the comment back to the subcommittee. Dr. Scheuer recommended that the metabolic syndrome, incorporating obesity, insulin resistance/diabetes, and hyperlipidemia, be noted.

Introduction (page 1) – Expand discussion of risk factor awareness.

Hilary T. O'Herlihy, M.D. commented that he was pleased to see racial and ethnic disparities included in the report. He stated that MedChi has established its own committee to address the issues raised in the Institute of Medicine report, and is working with Koreans, Filipinos, and American Indians, as well as African-Americans. Dr. Scheuer noted his concern that the discussion in the draft report is restricted to African-Americans, and said that it needs to be broadened.

Reduction of racial and ethnic disparities in cardiac care (page 2) – Broaden to include other populations.

Dr. Scheuer commented that the "Early identification and treatment of persons with out-of-hospital cardiac arrest" section (page three) addressed the issues of training people in the use of automated external defibrillators (AED); however, other issues are not covered, such as strategic placement of the AEDs, maintenance, and signage. Dr. Bass reported that MIEMSS is about to receive data from a two-year period that epidemiologists have been collecting, which identifies, among other elements, location of cardiac arrests. There are about 4,000 patients in the study. He stated that MIEMSS administers the AED program in Maryland. There are requirements that AED programs must meet, which include equipment and maintenance. A bill was introduced to mandate AEDs in certain locations; however, MIEMSS requested that the bill be deferred until more is known about their effectiveness in various locations. There is evidence of the effectiveness of public access to AEDs in airports and casinos; however, less is known about the effectiveness in office buildings, senior centers, and homes, for example.

Dr. Scheuer inquired if there was a way to tie the report recommendation into the MIEMSS program. Ms. Barclay reported that Lisa Myers, Director of Program Development at MIEMSS, is a member of the Long Term Issues Subcommittee and has provided much of the direction for AEDs. Dr. Bass stated that $12.5 million is available in federal grants to place AEDs in rural areas. MIEMSS has worked with nine eligible counties in Maryland to get the devices in those areas. Sidney C. Smith, M.D. inquired where Maryland had placed the devices in rural areas. Dr. Bass stated that they are located in places where people assemble and can be trained to use them; currently this is the most cost-effective strategy, although the vision is to have them located more widely.

Dr. Scheuer noted that the AED recommendation in the draft report should take notice of the MIEMSS AED Program and study. He suggested that the report include a recommendation to complete a feasibility or evaluation study on the issue of AED placement. Dr. Bass suggested that the Commission work with MIEMSS to continue to examine the issue, and then take the recommendations to the General Assembly.

Early identification and treatment of persons with out-of-hospital cardiac arrest (page 3) – Revise to incorporate study related to strategic placement of AEDs.

Dr. O'Herlihy expressed his understanding that the value of AEDs was that they are easy to use, and therefore do not require much training. Dr. Bass replied that people are required to complete a four-hour training session, followed by a four-hour course once a year if no drill (if drill, every two years). Dr. Bass reported on the O'Hare Study (Caffrey SL, Willoughby PJ, Pepe PE, Becker LA. Public use of automated external defibrillators. N Engl J Med 2002;347:1242-7), which found that AED operators who had no training or experience in the use of AEDs were able to resuscitate patients, however, with less success than those who had training.

Inter-Hospital Transport Subcommittee

Dr. Bass commented that the database referred to in item one of the recommendations is already being implemented by MIEMSS. He inquired if there were additional data elements required. Ms. Barclay asked if time-to-treatment was currently available in the data set. Dr. Bass replied that data is collected at the hospital level, not by EMS. He noted that it would be possible to require hospitals designated as a specialty center to submit data, and link the hospital and EMS data sets. Dr. Scheuer commented that door-to-balloon time is also important to collect. Dr. Bass inquired if MHCC could require that hospitals report such information. Ms. Barclay stated that the Commission could require hospitals to report, but would also need to link the data with EMS. Dr. Bass replied that it could work similar to the trauma data set, where the Maryland Ambulance Information System (MAIS) is used as a link (using MAIS number or probability to link).

Dr. Bass reported that the regulations discussed in item two, that is, nurse attendance for inter-hospital transports, have been finalized. Dr. Scheuer thought that there would only be a small number of cases where it would be necessary for a nurse to accompany a transport. Dr. Bass agreed, however, said MIEMSS needed to be cautious about the issue. Dr. Scheuer inquired about potential legal issues for transporting a patient without a nurse present. Dr. Bass stated that EMTALA requires that the sending hospital must ensure that qualified personnel with appropriate transportation equipment accompany the patient transported. The transport personnel must be qualified to handle potential complications or deterioration in the patient's condition that might occur during the transport. The sending physician has the responsibility to determine the appropriate level of care. MIEMSS addresses these issues through the regulations. Dr. Bass reported that data from the Hopkins Transport Program indicate that it is possible to identify patients at very low risk. Dr. Scheuer suggested that the recommendation be revised state "the circumstances, <u>if any</u>, where a nurse should be required…" Dr. Bass replied that the wording in the draft is correct.

Dr. Scheuer noted that the minutes for the Inter-Hospital Transport Subcommittee documented a discussion about the use of a single or regional phone number to assist in inter-hospital transports; however, this was not reflected in the draft report under item four. Ms. Barclay reported that there were initial discussions on a single point of contact; however, there was no consensus about its benefit, and it was consciously omitted from the report.

In regard to recommendation four, Dr. Bass noted that MIEMSS requires perinatal centers to have a contract with a transport service. Ms. Barclay said that is the intent of the recommendation. Baltimore hospitals have such an arrangement; the arrangement may be less formal in the Maryland suburbs of the Washington, D.C. area. Dr. Bass stated that it would be possible for MIEMSS to promulgate a similar regulation for a designated cardiac center.

Item four (page 2) – Revise to clarify the intent of the recommendation.

Dr. Scheuer, in commenting on recommendation three, said that the report should define the systems currently in place and how effective they are. Some areas of the state may be well served, and others not. He questioned if there should be an integration process for use by hospitals in all areas. Dr. Bass reported that MIEMSS has good data now. The system works by the sending hospital calling the receiving hospital. Once the receiving hospital accepts the transfer of the patient, it is responsible for sending an ambulance for the transport. However, in rural areas, the sending hospital may call for assistance from the local service. The 911-system is a separate entity, and 911-ambulances usually do not do inter-hospital transports, although they will in the case of backup (no commercial service available). Inter-hospital transports generally take longer than the average 911-call and takes the 911-team away from emergencies.

Item three (page 2) - Revise to describe the current system and its effectiveness.

Dr. Scheuer inquired if Dr. Smith wanted to comment on the first two draft reports, since he called in at 6:50 p.m. and missed the earlier discussions. Dr. Scheuer noted that the committee made no major changes. Dr. Smith said that he would review the minutes and add anything, if he thought it was necessary.

In regard to the quality measurement and data reporting, Dr. Griffith inquired what would be included in the aggregate data, how it would be used (in addition to activities related to quality improvement within each institution), and what data would be submitted to the Commission (how data in the "aggregate" report would be broken down). Dr. Baumgartner reported that the concept was that the data would be used for internal discussion among programs for quality improvement. He added that an MHCC member might be an ex-officio member and attend meetings. The report would present aggregate data, based on the Northern New England model. Each institution would have access to the more detailed data. Dr. Griffith asked if there was an implied prohibition on the use of the data for publicity (as a marketing tool). Dr. Bass stated that the medical review committee law contains confidentiality and immunity provisions. For all MIEMSS data, MIEMSS maintains the confidentiality of records, prohibiting the identification of any person or persons, including hospitals. MIEMSS regulations establish provisions for disclosure to: (1) an approved regional or State quality improvement program that is subject to the same confidentiality guidelines as MIEMSS; (2) a scientific research professional whose written research proposal is MIEMSS-approved with respect to scientific merit and confidentiality safeguards (data do not identify specific hospitals or patients); and (3) hospitals, public or private agencies, and other interested parties for prevention activities, epidemiological or demographic studies, or education and research projects (aggregate data). Dr. Griffith questioned what action the Commission would take if it acquired through its ex-officio representation on the committee knowledge that one or more institutions were continually under-

performing or not improving consistently. This especially presents difficulties if an MHCC member is present at the meetings. Ms. Barclay stated she was unsure if it was possible for MHCC to be an ex-officio member. She noted that the recommendation says "potential." More research must be done on that important issue. Both Ms. Barclay and Ms. McLean noted that MHCC funding would shift ownership of the data to MHCC. A number of issues require clarification in implementation.

Draft Report of the Quality Measurement and Data Reporting Subcommittee - Access to data (page 2) - Clarify the prohibition of use of quality improvement data for publicity.

4. Other Business

The next meeting of the Steering Committee will be held on April 14th, after the meeting of the Interventional Cardiology Subcommittee.

5. Discussion on Options for the Structure and Composition of an On-Going Advisory Committee

Dr. Scheuer stated that he thought the reports to date were excellent; however, they need to address the next steps of monitoring and evaluation. As an example, Dr. Baumgartner mentioned who will do periodic audits of individual programs. Dr. Scheuer thought there was a great risk that the work being done would lapse into obscurity if follow-up was not built into the current reports. He requested that each Steering Committee member and subcommittee member think about the processes required to monitor the recommendations made in the draft reports and to bring ideas to the next meeting (April 14). Dr. Scheuer also thought that additional clarification was needed on the funding of the activities. Ms. McLean stated that the activities of the Advisory Committee are mandated from the State authority; however, there is no money in the budget to fund them. It will take a combined public and private effort to achieve the goals. The lack of funding does not imply its importance as being undervalued.

Dr. Scheuer excused himself for an early departure at 7:18 p.m.

Dr. Griffith emphasized the importance of ensuring funding for process improvement to achieve the best possible cardiac care that is at the same time cost-effective. He inquired if the Northern New England model is entirely voluntary and self-funded. Dr. Baumgartner replied that the group was initially established without any grant money or other funding. However, grant money is now used to support its activities, for example from the American Heart Association.

Dr. Bass reported that MIEMSS has access to some funds. He said that MIEMSS has a medical review committee that currently looks at severity-adjusted outcomes data from the designated Trauma Centers, and MIEMSS takes action if necessary. MIEMSS will ask the hospitals to conduct a special review and return to MIEMSS with data if they are performing below par. Dr. Bass offered to meet with the Commission to discuss setting up a medical review committee.

Dr. O'Herlihy supported Dr. Scheuer's comments regarding the importance of a structure for following through with monitoring and evaluation.

6. Adjournment

The meeting adjourned at 7:20 p.m.

Summary of the Meeting
of the
Advisory Committee on Outcome Assessment in Cardiovascular Care

April 14, 2003
4160 Patterson Avenue, Conference Room 100
Baltimore, Maryland

Committee Members Present
James Scheuer, M.D., Chairman
Robert Bass, M.D.
Luther T. Clark, M.D.
Donald H. Dembo, M.D.
Bartley Griffith, M.D.
Jeffrey D. Jones, M.D.
Mark Midei, M.D.
Luis Mispireta, M.D.
Hilary T. O'Herlihy, M.D.
David O. Williams, M.D.

Committee Members Absent
William A. Baumgartner, M.D.
James L. Field, D.B.A.
Scott Friedman, M.D.
Steve B. Lowenthal, M.D.
Thom Mayer, M.D.
Eugene R. Passamani, M.D.
Nelson J. Sabatini (ex-officio)
Sidney C. Smith, M.D.

Members of the Public Present
Vanessa Aburn, Union Memorial Hospital
Paul Blackwood, Dimensions Health System
Clarence Brewton, MedStar Health
Sandra Mann, Johns Hopkins Medical Institutions
Vanessa Purnell, MedStar Health
Jack Tranter, Gallagher, Evelius & Jones

Commission Staff Present
Barbara G. McLean
Pamela W. Barclay
Bridget Glazebrook
Colleen Lates
Susan Panek
Debbie Rajca
Dolores Sands

1. Call to Order

James Scheuer, M.D. called the meeting to order at 6:05 p.m.

2. Approval of the Minutes of the Previous Steering Committee Meeting (March 26, 2003)

On the motion of Donald H. Dembo, M.D., which was seconded by Luis Mispireta, M.D., the minutes of the March 26th meeting were approved.

3. Subcommittee Reports

Dr. Scheuer began by stating that the goals of the meeting were to review the subcommittees' reports and receive any suggestions for amendment of the reports, and to open

the discussion regarding what happens after completion of the Steering Committee's work to make sure that it moves forward.

Interventional Cardiology Subcommittee

Dr. Scheuer noted that the Interventional Cardiology Subcommittee has produced two reports: (1) Acute ST-Segment Elevation Myocardial Infarction and (2) Elective Percutaneous Coronary Intervention, with the latter still a work-in-progress. He added that the one-year extension of the C-PORT exemption ends in July 2003.

David O. Williams, M.D., Chairman of the subcommittee stated that the subcommittee was presented with several charges investigating: (1) acute MI and primary angioplasty, and (2) elective angioplasty without on-site surgical backup.

Dr. Williams noted that there is a much larger base of knowledge on acute ST-segment MIs and primary angioplasty without on-site cardiac surgery backup, compared to elective angioplasty without on-site surgical backup. To assist in meeting the charge of the subcommittee, Chris Cannon, M.D., of Brigham & Women's Hospital, assembled a small committee to develop a state-of-the-science paper on the subject, and Tom Aversano, M.D., of Johns Hopkins, presented the results and experiences of the C-PORT trial and registry. Each question posed in the charge was discussed and answered based on current knowledge gained through research. The acute ST-segment elevation MI report was based on what is considered the best standard-of-care for patients in Maryland. Dr. Williams also pointed out the inclusion of the value of 12-lead ECGs in the field (page two) to enable diagnosis and appropriate triage, and that their use is important to current recommendations. He noted that it is now recognized that, when the two alternatives are equally available, PCI is superior to thrombolytics, in regard to better patient outcomes, with some constraints, e.g., timing and the circumstances in which PCI is performed. The report details those constraints. However, there is limited data comparing the benefits of PCI with or without surgical backup. Studies are not rigorous or detailed enough.

Dr. Williams summarized the report by noting that the Institutional Resources (pages 3-6) have been based on the guidelines of professional societies and experiences of C-PORT. The section about the relationship between volume of primary angioplasty procedures and outcomes (pages 6-7) was written from the latest literature. The report also describes which patient groups would be most appropriate to receive PCI in settings without on-site cardiac surgery (page 7), and outlines the necessity of on-going monitoring. Dr. Williams said that the subcommittee set reasonably rigorous standards for programs to do PCI, particularly for programs without surgery. An approval process is needed to initiate PCI, with a continued review and reapproval process. Dr. Williams noted that the subcommittee members commenced as a heterogeneous group with differing views; however, in the end the document was approved unanimously.

Dr. Scheuer noted that the report provided to Steering Committee members had no substantive changes.

Donald H. Dembo, M.D. noted that at the recent American College of Cardiology Annual Scientific Session in Chicago evidence-based medicine was presented to show that interventional

cardiology is far superior to thrombolytics; however, some flexibility is needed. C-PORT was a success in Maryland, despite some facilities not performing angioplasty 24/7; for example, Easton Memorial operated C-PORT on a part-time basis only, with the interventional cardiologist performing procedures elsewhere on other days. It is not unusual that angioplasty is not available 24/7. He also noted that inter-hospital transport plays an important role in primary angioplasty, and that even if the transport process took two hours, intervention resulted in a better outcome than immediately available thrombolytics. He reiterated that flexibility is needed, especially in rural areas.

Dr. Scheuer stated that the report sets standards and goals, and guides the development of primary angioplasty programs without on-site cardiac surgery backup; however, the document is not totally inflexible. Dr. Williams agreed that the report allows for some leeway. He stated that primary PCI should be performed 24/7, but in reality issues will arise to prevent this; however, facilities need to recognize the major commitment required. Dr. Williams said that a phasing in could be discussed; however, there's a relationship between outcome and volume. It is important to note that the report does not compromise patient care. Dr. Mispireta stated that the majority of patients are treated within the two-hour range at PCI programs in the state.

Jeffrey D. Jones, M.D. raised a question about the operator and institution volumes. Dr. Williams confirmed that the volumes used in the current report are the same as the ACC/AHA PCI guidelines (2001).

Dr. Scheuer raised again his concern that all C-PORT hospitals are not available to perform procedures 24/7, and that it should be the goal. He recognized that there will be times when an institution cannot meet that goal. Dr. Williams noted that 50 ST-segment MIs is not a small number of MIs for a lot of hospitals, and part of the goal for 24/7 was also to increase the potential volume of the program. Dr. Dembo said that access to 24/7 within two hours in Maryland requires institutional and transportation responsibility.

Dr. Williams noted that the Danish Multicenter Randomized Study on Thrombolytic Therapy versus Acute Coronary Angioplasty in Acute Myocardial Infarction-2 (DANAMI-2) study allowed up to three hours for transport; however, the majority was within 30 minutes. The study found that if time-to-PCI was greater than 120 minutes, the benefit was no greater than that of administering thrombolytics. Dr. Dembo noted that the use of 12-lead ECG to assist diagnosis on the scene helped reduce transport time. Dr. Williams agreed that 12-lead ECGs are the cornerstone to the process, and that is reflected in the report.

With regard to elective angioplasty, Dr. Williams noted that when elective PCIs were first performed there was a high need for cardiac surgery backup or rescue (approximately 50 percent in 1978); however, this need has decreased to around 5 percent in 1998 to only 1 percent or less today. There is no firm data that demonstrates that the procedure is safe without backup surgery; there is no evidence of clinical benefit for patients to have PCI at a hospital without backup surgery. The benefit is one of convenience. The subcommittee felt it was reasonable that, if a research effort like C-PORT was identified, the Commission should consider an application from a hospital to participate in such a project. The Commission would have the obligation of making sure that the trial was sound and legitimate.

Dr. Williams left the meeting at 6:30 p.m., after concluding his report.

Dr. Scheuer suggested that the report should recognize that it is difficult to commence operation 24/7 at the initiation of a program, but is important for access that 24/7 is the goal of any program. He will ask Dr. Williams to incorporate a statement to address the issue raised about outlying hospitals and achievement of the 24/7 goal over a not-too-distant time. Dr. Mispireta agreed that there is value to 24/7 on-site care, which was worthwhile pursuing in the future. Mark Midei, M.D. said that there would regional difficulties in achieving a 24/7 program; he noted that this may be physician-driven in rural areas, or shortages in technical support in Baltimore City. He added that with an ever-expanding number of programs to draw from that same pool, coverage is going to be onerous and very expensive. Dr. Scheuer questioned if a program should continue to operate if it cannot provide 24/7 service. Dr. Midei said that, looking retrospectively, in the past month, no C-PORT program provided coverage 24/7. Dr. Scheuer noted that the report states all operators doing primary PCI must participate in an on-call schedule. Dr. Dembo agreed that it is generally possible to find a cardiologist to do a procedure, but difficult to find support staff. He added that payers are beginning to look very carefully at length of stay as a determinant, and programs are experiencing a loss of funds if the procedure is not performed in an expedited manner.

Dr. Dembo wanted to know whether the recommendations in the report will be published as guidelines, goals, or absolute requirements for approval. Dr. Scheuer replied that the report sets forth standards that should be met. Dr. Mispireta said that the goal of 24/7 may stimulate sharing resources among programs. Dr. Scheuer added that the report states that the hospital administration must make a commitment to try to achieve this goal.

Noting that it is almost impossible to achieve adequate numbers without operating 24/7, Dr. Midei supported the goal to operate 24/7. He said that the goal of 50 transmural infarcts will lead to improved quality. Dr. Midei also raised the issue of accreditation. He described a previous situation in which interventional treatment occurred during the day, and thrombolytics during the evening, which was purely for the convenience of physicians. Dr. Bass said that MIEMSS could incorporate the guidelines into a regulation to identify cardiac referral centers. He said MIEMSS would track confidential data, including data on the hours of availability, and its impact on quality. MIEMSS would tell commercial ambulances and helicopters transporting a patient for a higher level of cardiac care to go to one of these referral centers. If a hospital's quality was not on target, it would be possible to remove its designation as a referral center. Eventually, the criteria of operating 24/7 may be included in regulation as part of a continued process and dialogue with an ongoing committee.

Dr. Scheuer suggested that the committee members accept the report in principle with the caveat that a statement should be added for new programs to phase in 24/7 care and to meet minimum volumes. This could be evaluated and monitored by the State by a process established by the Advisory Committee.

Dr. Dembo said that it may be that this ideal in providing care for this group of patients is achievable, but there are barriers that have to be overcome. Dr. Scheuer noted that some of the criteria are minimal; further, the criteria will change as new data become available.

Dr. Scheuer said that he would bypass the elective PCI report, as it was still a work-in-progress. He noted that the main components of the report will remain the same, which include the point of convenience versus clinical benefit of elective PCI at facilities without cardiac surgery backup, and the research question of safety with any approval to be part of an investigative process; further topics discussed at the earlier meeting tonight included cost-effectiveness and the financial impact on existing facilities and the role of transport. Dr. Dembo inquired whether a distinction had been made between elective and urgent PCI (acute coronary syndromes that are not ST-segment elevation). Dr. Scheuer said that had not been addressed, although he would consider urgent as requiring early but not acute (120-minute) intervention. The issue is timing.

Quality Measurement and Data Reporting Subcommittee

Dr. Mispireta, Chairman of the Quality Measurement and Data Reporting Subcommittee, reported that the document has not been altered. The structure of the process has been designed to maximally protect the data: participation is voluntary, an independent consortium will be set up, and data shared with the Commission will be in aggregate form. STS data elements will be used.

Pamela Barclay identified two issues in the committee's earlier comments: (1) confidentiality of data, and (2) method of sharing data with the Commission. Barbara McLean provided an update on House Bill 164 - Medical Review Committees. HB164 was passed with a two-year sunset, i.e., the Commission within two years must designate a patient safety center. Ms. McLean noted that the grant application is still pending with AHRQ. If the grant is not forthcoming, it would be possible to collect data under MIEMSS, which has a Medical Review Committee status.

Dr. Mispireta confirmed the difficulty he had in bringing the interventional cardiologists together to meet. He stated that the concept outlined for cardiac surgery will be implemented, and then expanded to interventional cardiology later. Dr. Scheuer agreed that was a good path to follow; however, a statement must be incorporated into the final report. He added that part of the concept in the acute ST-segment elevation report is the collection and evaluation of data associated with primary PCI.

Dr. Scheuer inquired how the consortium would deal with the possibility that a hospital performed badly. Dr. Mispireta reported that the data would be collected for quality improvement purposes only, not for punitive purposes. He would not anticipate regulatory action being taken because of the data. Bartley Griffith, M.D. agreed with Dr. Mispireta, and complimented the subcommittee on the marvelous job; however, he expressed concern about what the State would do if a hospital performed poorly, especially from a liability aspect. This becomes an issue if there is an MHCC representative auditing the consortium. Dr. Mispireta and Ms. McLean said that the Commission will not receive any hospital-specific information. Dr.

Bass noted that MIEMSS has an ongoing review process for designated trauma and specialty referral centers. If an issue is raised about poor performance, the hospital is requested to resolve the issue, or it will be removed from the designation list. No hospital has ever been removed from the list; however, if a hospital was removed, it could appeal through due process or reapply to be designated. Dr. Griffith re-inquired what the consortium would do about a non-performing center that was refractory to improvement. Dr. Mispireta acknowledged Dr. Griffith's point, but stated he was unsure if the MIEMSS process would work for cardiac services, as there is a smaller percentage entering the system through the emergency medical system. He noted that the model being recommended for Maryland is based on the Northern New England Cardiovascular Disease Study Group, which seems to work well. Wisconsin and Minnesota, he said, use a similar model.

Dr. Scheuer recommended that the committee accept the report, with the addition that the process to deal with outliers be reviewed periodically. The suggested mechanism is for the problems or outliers to be self-correcting; otherwise, other processes should be developed and implemented if the hospital does not improve. Luther T. Clark, M.D., who is a member of the New York State Cardiac Advisory Committee, suggested that definitions might be needed to define outliers and standards need to be in place to remove a program from the consortium if needed. If a hospital is consistently non-performing, it is imperative that the consortium is able to deal with the program. In fairness to the participating programs, the process for addressing outliers should be known to them, as well as any criteria that would lead a program to be removed from participation. These measures may even evolve. Dr. Bass agreed that the process was important, but perhaps more important are outcomes. Dr. Mispireta replied that the consortium was an evolving process, with the concepts defined. He said that the finer details would be addressed later when the consortium is implemented. Hilary T. O'Herlihy, M.D. commented that the consortium would have responsibility to Maryland citizens, and it needs to be very specific about what must or should be done.

Dr. Dembo inquired what authority this or a future committee would have for any kind of disciplinary action. Dr. Bass replied that MIEMSS has statutory authority to designate hospitals, i.e., make a list of hospitals, based on performance, and regulations under COMAR Title 30. Under the regulations, MIEMSS can act on certain events, with due process, and constrained by time limits. The hospital has a right to appeal to the EMS board, which oversees MIEMSS.

Dr. Mispireta noted that for trauma centers removal from the designation list would basically close the program, because 80-90 percent of the volume is generated through the emergency medical system. This would not be the case for cardiac surgery or interventional cardiology programs. Dr. Mispireta estimated that about 10 percent of those patients come through the MIEMSS route. Dr. Bass said that approximately 40 percent of acute MI cases would come through the emergency medical system.

Dr. Scheuer recommended that set programs from STS could be used by an ongoing group to develop criteria to identify and monitor outliers. Dr. Mispireta stated that it would be easy to identify outliers; the issue is resolving the problem. If there were a failure, the consortium would then need to develop the process. Dr. Scheuer stated that there should be an ongoing process to review that committee's work. Dr. Dembo inquired what would happen to

any program that consistently performed below the criteria. Currently, there is no way to address the issue through disciplinary action such as decertification. Ms McLean mentioned other vehicles like the Commission's hospital report card. Dr. Scheuer noted that the subcommittee has made a commitment not to take a punitive approach. Dr. Mispireta stated that if a program had low volumes, with good outcomes, there was no need for action; however, if a program had high volumes and low outcomes there would be a need for action. He said that the State has no outcomes data now. The proposal includes a number of validation processes for data.

Dr. Scheuer recommended that the report be accepted with some changes, consistent with tonight's discussion. Dr. Mispireta was willing to accept the need for an ongoing process.

Inter-Hospital Transport Subcommittee

Dr. Jones, Chairman of the Inter-Hospital Transport Subcommittee, noted that some minor changes were made to the report as a result of the last meeting. He noted that 12-lead ECGs needed to be taken into consideration, following the recommendations of the Interventional Cardiology Subcommittee. Maryland is geographically diverse, and there is a need for air and ground transport. With an integrated system of air and ambulance transport, it is possible to keep transport time within 90 minutes.

Dr. Jones noted that initial discussions were made on recommending a single telephone number, but thought free enterprise would restrict its possible success statewide. Dr. Bass disagreed with the idea that a one-number call is impossible. Dr. Jones inquired whether the commercial companies would cooperate. Dr. Bass stated that if the companies were primarily commercial, they could be called on a rotational basis (similar to a process used by the State Police with tow trucks). Dr. Scheuer inquired if there are other states to serve as models. Dr. Bass replied that no other state has a similar model, and that Maryland is unique. The Communications Center is 24/7. The system currently does not track commercial flights, but this would be possible with a GPS device. Dr. Jones expressed concern that a central dispatch may have an inherent delay. Dr. Midei noted that there is not a huge patient volume involved. Dr. Bass said he did not want to leave the impression that it is impossible to set up a single statewide contact point. Dr. Bass added that two companies now operate four helicopters, and the State Police are phasing out of commercial service. Scene work is becoming primary, not interfacility transport. Dr. Bass indicated a willingness to study a single number for all transport. Ms. Barclay noted that some of the commercial services appeared to be apprehensive about the idea during preliminary discussions, but perhaps more dialogue about how it would work was required.

Dr. Dembo inquired what community hospitals that presently have a significant number of chest pain referrals think about being bypassed, and whether the open heart surgery centers, with or without 24/7 interventional care, can accept all the patients who potentially have a need. He expressed concern if the open heart surgery hospitals would be able to handle all the patients; and wondered how to best distribute patient load. Dr. Bass noted that 45,000 transports per year statewide are for chest pain patients, and approximately 10,000 are candidates for PCI. Fifty percent of patients arrive at the hospital by ambulance and about 50 percent by private vehicle. Potentially, data is available to further look into patient distribution.

Dr. Mispireta inquired about the annual volume of primary angioplasty. Ms. Barclay replied that the C-PORT hospitals do approximately 300 per year; however, it is not possible to determine the volume at open heart surgery hospitals because the ICD-9 coding does not separate primary and elective angioplasty. Dr. Midei offered that, in a global sense, about 20 percent of the patients discharged with acute infarction have transmural injury on admission. About half of those get direct intervention (angioplasty).

Dr. Scheuer recommended that the Inter-Hospital Transport Subcommittee meet again to finalize the last changes. Dr. Bass invited the subcommittee to meet at MIEMSS, and MIEMSS can show its communications center. Dr. Jones accepted the offer.

Long Term Issues Subcommittee

Dr. Scheuer noted that Eugene R. Passamani, M.D., chairman of the subcommittee, was not present tonight. The report still needs to be updated from the last Steering Committee meeting, therefore, no discussion was held.

4. Other Business

There was no other business.

5. Discussion on Options for the Structure and Composition of an On-Going Advisory Committee

Dr. Scheuer distributed a draft to all members to discuss for inclusion in the report to describe the process to implement the Steering Committee's recommendations and to evaluate the ongoing progress to achieve the major goals contained in the final report. Dr. Dembo moved to accept the additional wording, and the motion was seconded by Dr. O'Herlihy. Dr. Bass added that mention of EMS or MIEMSS should be included in long term issues because MIEMSS will be involved in centralized coordination.

Dr. Dembo reported that at the ACC meeting research was presented showing that despite the success of statins at preventing AMI, a large percentage of patients are not receiving adequate treatment for coronary heart disease, which is a major cause of congestive heart failure, a condition discussed in the Long Term Issues report. He stated that there is not adequate attention being paid to preventative measures. Dr. Scheuer agreed and stated that the Long Term Issues Subcommittee needs to incorporate more information about metabolic disorders, such as obesity, which speaks to part of the concern.

6. Adjournment

The meeting adjourned at 7:45 p.m.

DRAFT

Summary of the Meeting
of the
Advisory Committee on Outcome Assessment in Cardiovascular Care

June 2, 2003
4160 Patterson Avenue, Conference Room 100
Baltimore, Maryland

Committee Members Present
James Scheuer, M.D., Chairman
Robert Bass, M.D.
William A. Baumgartner, M.D.
Donald H. Dembo, M.D.
Steve B. Lowenthal, M.D.
Mark Midei, M.D.
Luis Mispireta, M.D.
Hilary T. O'Herlihy, M.D.
Eugene R. Passamani, M.D.
Nelson J. Sabatini (ex-officio)
David O. Williams, M.D. (via telephone)

Committee Members Absent
Luther T. Clark, M.D.
James L. Field, D.B.A.
Scott Friedman, M.D.
Bartley Griffith, M.D.
Jeffrey D. Jones, M.D.
Thom Mayer, M.D.
Sidney C. Smith, M.D.

Members of the Public Present
Vanessa Aburn, Union Memorial Hospital
Paul Blackwood, Dimensions Health System
Sean Flanagan, St. Joseph Medical Center

Commission Staff Present
Barbara G. McLean
Pamela W. Barclay
Bridget Glazebrook
Kristin Helfer-Koester
Colleen Lates
Susan Panek
Debbie Rajca
Valerie McRae
Dolores Sands

1. Call to Order

James Scheuer, M.D. called the meeting to order at 6:20 p.m. He introduced and welcomed the Honorable Nelson J. Sabatini, Secretary of Health and Mental Hygiene, who was appointed by Governor Robert L. Ehrlich, Jr., and was most recently Executive Vice President of the University of Maryland Medical System.

2. Approval of the Minutes of the Previous Steering Committee Meeting (April 14, 2003)

On the motion of Steve B. Lowenthal, M.D., which was seconded by Hilary T. O'Herlihy, M.D., the minutes of the April 14th meeting were approved.

3. Subcommittee Reports

Dr. Scheuer began by stating that the goals of the meeting were to review the subcommittees' reports and receive any suggestions for amendment of the reports.

Interventional Cardiology Subcommittee

Dr. Scheuer noted that David O. Williams, M.D. led the Interventional Cardiology Subcommittee, and that he is one of the leading interventional cardiologists in the country. Dr. Williams was very active in helping the ACC/AHA to define their guidelines for interventional cardiology. Dr. Scheuer stated that there were 26 members on the subcommittee, who endorsed the report virtually unanimously. He then opened the discussion of the report.

Eugene R. Passamani, M.D. commented that he had read the report carefully, and stated that it was well-written. He felt that, for the purposes of the discussion, it would be useful to separate the report into primary angioplasty and elective angioplasty.

In regard to the primary angioplasty component of the report, Dr. Passamani described that portion as very well done and carefully considered. He had no other comments, except to suggest that the Commission should consider the metrics at the end of the recommendations as potential Report Card elements.

Donald H. Dembo, M.D. stated that he agreed with the concepts of the primary angioplasty report. He reinforced the issue that it is now well established that primary angioplasty has better outcomes than thrombolytics; however, access in some (rural) regions of the State can be a problem. He recommended continued support of primary angioplasty where there is careful monitoring, skilled and experienced individuals perform the procedure, and the institution provides proper support.

Dr. Scheuer reported that discussions with Sidney C. Smith, M.D. and within the ACC and AHA indicate that the guidelines may change as they monitor new information within the next year. As facts and data change, there should be an appropriate mechanism to keep the policies recommended in the report up-to-date. He suggested that a statement be included requiring that the Commission review and re-evaluate the policies on at least a yearly basis, to ensure that as research and knowledge change (e.g., 120 minutes as maximum door-to-balloon time, and number of cases for minimum physician volumes), the recommendations remain current. Dr. Williams acknowledged that this was a good idea, and noted that the report presented was addressing the issue of process and the specific questions within the charge provided. The subcommittee took the information currently available at the time and answered those questions. Where the knowledge base changes, including surgery and other areas, it is appropriate to reassess policy periodically on a regular basis. Dr. Scheuer noted that as part of the overall report, the Steering Committee recommended an ongoing advisory committee to review standards, reports on data, and similar issues. He suggested that the ongoing advisory committee could add to its charge the ongoing review of criteria to reflect changes nationally.

Dr. Scheuer requested endorsement of the acute angioplasty portion of the report. Dr. Passamani moved approval with the added suggestion that the Commission consider the metrics for Report Card elements. Hearing no objections, Dr. Scheuer expressed the committee's hearty support of this component.

Dr. Scheuer commenced the discussion on the elective angioplasty component of the report. He stated that this really speaks to whether elective PCI is in an individual patient's best interests, or has the potential to improve the quality of an individual patient's care since the patient has the time to go to multiple centers. It also addresses the situation that if an institution or a group of institutions wish to start an elective program, whether it should be as an investigational program rather than routinely provided approval by the State. The report sets out some guidelines for developing an investigational program. Dr. Passamani responded that elective angioplasty without surgical backup is a controversial area. He expressed concern about the design and implementation outlined in the draft report (dated 5/16/2003), in particular, the lack of reference to requiring a control group in the pilot study. He noted that C-PORT, which formed a basis for the proposed research, had a control group; individuals were randomly assigned to either primary angioplasty or thrombolytic therapy under carefully controlled circumstances. He added that 2,500 was the initial sample size, which C-PORT was unable to reach because it was unable to get funding for the study. Without randomization (i.e., a registry or case series), it is difficult to know what the comparison is. Dr. Passamani said that it is unlikely that a new program could have better outcomes than a large institution that has an ongoing program in conjunction with surgery. Given the control that Maryland has on the number of centers, all of the elective angioplasty centers are relatively high-volume centers. He also expressed concern about the large number of participants who would be required for such a study, in order to obtain statistically significant results. The endpoints will be death or MI, which are unusual events in all sorts of angioplasty. Dr. Scheuer agreed that the design in the report should include the need for a control group. He also stated that he would want a power analysis performed to determine the appropriate number of participants.

Dr. Williams described what the subcommittee looked at as its role in addressing the issue of elective angioplasty. The subcommittee wanted to make two points: (1) There is currently no data now to justify elective angioplasty being performed at hospitals without on-site surgery backup. There is a paucity of data, but it is insufficient to recommend this on a clinical basis. (2) The only benefit to the patient would be one of convenience. The subcommittee does not imagine that there is any clinical benefit whatsoever. The subcommittee wanted to emphasize that important point, as well as the issue of safety. Patient safety would have to be assured. In terms of a clinical trial, the subcommittee felt that, even with those considerations, a trial may be done safely under the proper circumstances, with the right protocols, patients, and institutional and clinical support. Such a trial would be a reasonable alternative for certain patients. It would require a clinical trial that does not yet exist to demonstrate that. Should such a quality trial emerge, it would be reasonable to allow hospitals in Maryland to participate. If such a study was done, prior to any implementation or change in policy, the results of the trial would have to be scrutinized. The subcommittee put in a check-and-balance system; however, it did not consider its assignment to design a trial.

Dr. Williams agreed that the features of a good trial as included in the report were not inclusive, and were meant to be illustrative, and that a robust trial would include many more components. Dr. Williams concluded by saying that this component, in part, was a response to what the subcommittee detected as a wave of enthusiasm by the nonclinical community to initiate elective angioplasty at hospitals without cardiac surgery.

Mark Midei, M.D. complimented Dr. Williams on the skill in crafting the policy, but was also concerned about the vagueness of the trial, and felt it reflected the difficulty in gaining consensus. He said that if the purpose of the trial is to prove safety of elective angioplasty without surgery backup, it is not possible to ensure safety of the patients. Dr. Midei said that he provided a dissenting opinion on the subcommittee with regard to enthusiasm for doing this. He suggested that, rather than leave the vagueness in the report, the Steering Committee might strongly consider adding structure to any trial (for example, try to set down the goals the trial is attempting to study, or figure out what variables are being tested). He said that the study is attempting to create a methodology for performing angioplasty outside of surgical centers that approaches equivalence with surgical centers.

Dr. Scheuer noted that there are other trials happening in other places, and questioned if Maryland should wait to see those results. William A. Baumgartner, M.D. inquired where these trials were taking place. Dr. Scheuer replied that he did not know all the details, but there is a demonstration pilot project involving three hospitals in West Virginia, and a trial at the Mayo Clinic in which interventional cardiologists are sent out to its satellite hospitals.

Based on the proposed study and experience with C-PORT, Dr. Baumgartner said even if the issue of safety is put aside, there are a number of logistics that will be difficult, namely, accumulating the number of participants needed, enrolling patients, and paying for the cost of the trial. Dr. Scheuer agreed that due to the number of endpoints possible for elective angioplasty and the kind of patients who would be chosen for a nonsurgical center, a large number of participants will be required to gain statistical significance. He stated that there are three alternatives available: (1) open up the State to allow elective angioplasty without backup surgery, with no trial, (2) allow a robust trial to be conducted, or (3) keep the current policies. Secretary Sabatini suggested that there may be a fourth option available, open up the State to allow more cardiac surgery programs. Dr. Scheuer noted that was an interesting option, but stated it would require establishing another subcommittee to perform the kind of detailed review that the Interventional Cardiology Subcommittee did. He suggested that that the committee needed to consider the current proposals.

Dr. Dembo agreed with Dr. Scheuer that oversight is required on a continuum and not every two years. He stated that his concerns were primarily (1) expense, (2) dilution of patient volumes at other large institutions currently performing elective angioplasties, and (3) litigation (related to informed consent and patient safety with ACC/AHA Class III indications). He noted that any physician would be able to convince a patient to provide informed consent for elective angioplasty without backup surgery. On the issue of convenience, he recalled a personal experience, and noted that the patient and family wish to go to the best institution (and not necessarily the nearest) available at the time, despite the perceived inconvenience. This is particularly the case as the patient population becomes more sophisticated and understands the

meaning of quality. Dr. Dembo continued that the mission of the Commission is to assure health care that is high quality, provides good access, and is affordable. He noted that quality, access, and cost are not an issue for elective angioplasty. Dr. O'Herlihy noted that similar arguments were made initially for primary angioplasty without backup. He said that he is in favor of considering elective angioplasty at hospitals without cardiac surgery if guidelines are established and selection of patients is done extremely well. He also questioned at what point the benefit of increased volumes levels off and does not result in improved outcomes. Dr. O'Herlihy said that convenience is an important advantage to individual patients, because a significant number of patients do not want to leave their county.

Dr. Dembo stated that it is not possible to accurately assess the risk for each patient, and expressed concern about exposing patients to an unsafe environment if there is no clinical need. Dr. Passamani clarified his position on the proposed trial, that he does support a trial being conducted before allowing elective angioplasty without surgical backup; however, it needs to be recognized that it is a complicated study, with high numbers required to test the hypothesis that a center without surgical backup which currently does not perform elective angioplasty can match the outcomes of the high-volume cardiac surgical center. He stated that a registry is not enough; the study must randomize patients to one or the other.

Pamela Barclay noted that the discussion in the report, commencing on page 21, establishes a framework for a clinical trial to evaluate the kinds of questions being discussed, and that the charge to the subcommittee was not to design a trial, but recommend what the Commission should consider with the assistance of an advisory committee. The subcommittee recommended that a number of points be considered, at a minimum (page 22):

1. Detailed description of the research design and methods;
2. Protocols for including patients;
3. Need for institutional review board review (patient safety and informed consent are paramount);
4. Criteria for participating hospital sites and physicians (e.g., minimum volume standards);
5. Data collection and management;
6. Timetable for initiating and completing the study (including how many patients and how long it will take to do the study); and
7. Source and amount of funding required (identify funds for the study).

Ms. Barclay noted that Maryland contributed greatly to the policy literature regarding primary angioplasty, and she asked whether Maryland wanted to contribute in the same fashion to the literature about elective angioplasty, an issue that is likely to continue to be debated nationally in the next several years.

Dr. Williams also emphasized that the subcommittee put two safety checks in the report, namely, (1) if protocols are developed, an expert committee must rigorously scrutinize and ensure the merit and appropriateness of the study, and (2) if such a study were done, the results would be reviewed again by the committee before any policy changes occurred. Dr. Williams noted that Maryland, in the past, has stood out in terms of the AMI experience, which was bold

and unique. He said that previously no patient went home immediately after a diagnostic catheterization, and that the thinking was that there was no clinical benefit for the patient to do so. Research has changed, and will continue to change, medical practices. It is important to keep an open mind.

Dr. Scheuer reminded the members that the Steering Committee needed to come to a consensus on the concept of allowing elective angioplasty in Maryland under an approved research format. Dr. Dembo again expressed concern that the question of "why" had not been answered. Dr. Baumgartner reminded the group that the point of the charge was to allow research trial protocols to be submitted, and that a research trial may not necessarily be approved. Dr. Williams agreed that if the experimental design were judged to be inadequate, the committee would have the ability to say "no."

Dr. Midei stated that there needs to be more reason than just convenience for the patient, before contemplating and approving a trial. He thought it would be better to wait and see the results in West Virginia before moving on any research in Maryland. Dr. Lowenthal noted that if C-PORT had been "bogged down" with "why," it may never have gotten off the ground. He also noted that cardiac surgery is plateau-ing and shrinking in volume, and will even more as interventional technologies and skills improve over the next 5 to 10 years. Dr. Lowenthal said that Tom Aversano, M.D. is very emphatic on tight controls of research studies. Dr. Midei maintained that the patient needs a defined clinical benefit, which currently does not exist. In C-PORT, there was the question of whether angioplasty was better than thrombolytic therapy. He asked what would be considered a successful outcome in the trial – if, for example, the patient outcomes in a nonsurgical center were better than those in current (surgical) institutions. Dr. Scheuer stated that the result that the study would be looking for was that there was no statistically negative outcome for performing elective angioplasty in hospitals without backup surgery. Dr Baumgartner said that he would leave it to the Commission to form the committee as it has done in the past.

Dr. Scheuer stated that the concept was to allow for a clinical trial that would be acceptable to the Advisory Committee. Dr. Passamani agreed with the concept, but wanted to add wording about a detailed description of the research design and methods, including the requirement for an adequate control group.

Dr. Williams restated the charge of the subcommittee slightly differently than Dr. Scheuer. The charge included:

- Should the Commission consider a pilot project study to assess whether it would be appropriate to modify current policy regarding the availability of on-site cardiac surgery backup for certain groups of elective angioplasty patients?
- How should this pilot project be designed and implemented? What would be the resource and program development requirements for a participating hospital?
- Which patient groups would be suitable for inclusion in a pilot program study of elective angioplasty?

If the Steering Committee endorses the report, it would be endorsing a process.

Dr. Scheuer inquired what would happen if West Virginia approached a Maryland hospital to join its current study. Dr. Williams responded that according to the report, the Maryland hospital would apply to the Commission for permission and the Commission would establish a committee to review the study design and respond with a recommended yes or no. Secretary Sabatini added that West Virginia would also have to request to expand and conduct its study in Maryland. There should be two aspects to participation: first, West Virginia; then the hospitals in Maryland that would like to participate.

Luis Mispireta, M.D. noted that a request for a clinical trial could be initiated in- or out-of-state, and the issues remain the same. He said that everyone probably has some form of concern about performing elective angioplasty without surgical backup, and the proposal as is is a quest for knowledge. Dr. Mispireta expressed that it may be necessary to include an addendum to the Steering Committee report to appease the differences and concerns of the group. He stated that the biggest obstacle he sees is the large volumes required to gain a statistically significant result. Dr. Baumgartner noted that the numbers required cannot be known until the research design is determined.

Dr. Scheuer agreed that the report would be amended to include that the research proposal must meet the highest standards of clinical investigation, which the Steering Committee understands means at least in terms of multicenter trials, power analysis, well-defined endpoints, inclusion and exclusion criteria, and randomized control. In addition to the highest experimental design, the committee to evaluate the study should represent individuals experienced in the design and evaluation of clinical trials. Dr. Williams noted that it is difficult to define the design of the study, and that an expert committee must approve the study. The sentiment that should be conveyed is one of quality. He said that the Steering Committee may want to define simply, or in very general terms, the qualifications of the review committee or what the review would be like. The Committee cannot anticipate every possibility. Dr. Williams excused himself from the meeting at 7:25 p.m.

Dr. Scheuer inquired about the level of support for the report. Dr. Baumgartner stated that he supported the report. Dr. Midei stated his reservations about supporting a trial that has no recognized clinical benefit. Drs. Baumgartner and Lowenthal agreed that the purpose of the expert committee reviewing the clinical trial protocols was to determine potential clinical benefits. Dr. Scheuer stated that it may be possible that excessively high volumes in large institutions, beyond a certain number of cases, may have a negative impact on outcomes, if patients are treated in an assembly-line fashion. If this was the case, introducing elective angioplasty at hospitals without surgical backup may have a clinical benefit. Dr. Scheuer commented that he would welcome a minority report.

Dr. Dembo noted that the C-PORT trial did ask "why," and there was a good clinical reason – muscle is time, and it did address the issues of quality, access, and cost. He noted that if the Steering Committee endorses the concept, his would be a dissenting voice, not approving but not disapproving the report. Dr. Scheuer noted Dr. Dembo's position and invited him to include an addendum about his concerns. Barbara McLean requested that any minority opinion should

be submitted within the next week because the report will be presented to the Commission on June 19th.

Dr. Scheuer stated that there was general agreement on the elective angioplasty component of the report, with the additions incorporated.

Long Term Issues Subcommittee

Dr. Passamani noted that the subcommittee held its last meeting a couple of months ago, but the draft report was not ready; however, it will include five major points:

1. The Commission should consider establishing a goal for morbidity and mortality from cardiovascular disease. Marylanders are currently ranked about mid-way in regard to cardiovascular health, compared with all states in the country. The aim is to improve on this positioning, to be either in the top 5 or 10.
2. In terms of how to achieve that goal, the Commission should consider studies in several areas. Further research needs to be completed, and a recommendation is included for a congestive heart failure (CHF) trial. Early in its sessions the subcommittee received extensive testimony on outpatient management of CHF.
3. Better overall management of known risk factors is needed, for example, hypertension and diabetes. Tom Nolan, Ph.D., of the Institute for Healthcare Improvement, spoke to the subcommittee about his experiences with risk management and improved outpatient delivery of preventive care.
4. Continued efforts within the African-American and other minority communities are necessary. Diane Becker, MPH, Sc.D., of Johns Hopkins, presented to the subcommittee research she has successfully been involved with to improve health outcomes for minority communities.
5. Knowledge and research about women's cardiovascular health should be improved.

Dr. Scheuer thanked Dr. Passamani for his role as chairman of the Long Term Issues Subcommittee and asked if the Steering Committee members had any comments. Dr. Dembo responded that cardiovascular risk (e.g., metabolic syndrome) is epidemic in the United States. He said that the level of obesity is increasing and 60 percent of the American population is significantly overweight.

Quality Measurement and Data Reporting Subcommittee

Dr. Mispireta, Chairman of the Quality Measurement and Data Reporting Subcommittee, reported that the subcommittee has not met since its report was offered at the last Steering Committee meeting. The report stands as it was then. Ms. Barclay said that a subcommittee report similar to that of the Interventional Subcommittee is in the process of being prepared.

Inter-Hospital Transport Subcommittee

Dr. Scheuer noted that Jeffrey D. Jones, M.D., Chairman of the Inter-Hospital Transport Subcommittee, was not present. Ms. Barclay reported that the subcommittee met on May 28, 2003 and finalized its recommendations.

Dr. Bass noted that Richard L. Alcorta, M.D., State Medical Director for MIEMSS, attended the last meeting as a representative for the agency. Dr. Bass reported that MIEMSS and EMS providers across the state are very willing to do whatever is needed to make the system better with respect to acute coronary care and getting the right patients to the right hospitals in the right time frame. They will use the existing communication system and form partnerships particularly with the cardiac referral centers. Perhaps the commercial ambulance industry, which principally does the inter-facility transports, can have ambulances on a standby basis to achieve the response times needed. Other issues include 12-lead ECGs in the field, information about which hospitals offer PCI, processes related to data and quality improvement, and monitoring and addressing the times that a hospital is unable to accept and take care of patients. MIEMSS and the providers are willing to work on these issues and be flexible to meet the goal of transporting patients expeditiously.

4. Other Business

There was no other business.

5. Adjournment

The meeting adjourned at 7:40 p.m.

4160 Patterson Avenue
Baltimore, Maryland 21215
Telephone: (410) 764-3460
Toll Free: 1 (877) 245-1762
TDD: 1 (800) 735-2258
FAX: (410) 358-1236
www.mhcc.state.md.us